

Medications for Treating Low Back Pain in Adults. Evidence for the Use of Paracetamol, Opioids, Nonsteroidal Anti-inflammatories, Muscle Relaxants, Antibiotics, and Antidepressants: An Overview for Musculoskeletal Clinicians

Clinical decisions for low back pain (LBP) are often based upon treating the underlying causal mechanism; however, the absence of a known mechanism for the majority of LBP patients makes treatment challenging. Clinicians must make an assessment of what treatment is most appropriate, given the duration and severity of the patient's LBP.

Most clinical practice guidelines for LBP recommend first-line treatment of

reassurance and advice to remain active, exercise, and engage in multidisciplinary rehabilitation and, where appropriate, the time-limited use of specific medications.²⁷ Medication options include paracetamol,

nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, muscle relaxants, antibiotics, and antidepressants. Given the adverse event risks associated with medications, clarity for clinicians on the evidence regarding risks and benefits of medication for LBP is warranted. In this paper, we provide an up-to-date overview for musculoskeletal clinicians on the evidence for 6 main medication types as well as their risks and benefits in the context of managing LBP.

Clinical Question

How effective and safe are paracetamol, NSAIDs, opioid analgesics, muscle relaxants, antidepressants, and antibiotics for reducing pain and disability in people with acute or chronic LBP?

Paracetamol (Acetaminophen)

Paracetamol is 1 of the most common medications used to manage pain.⁹ Paracetamol's mechanism of effect has been attributed to an ability to inhibit the cyclooxygenase pathway in the central nervous system, reducing the production of pain-mediating prostaglandins.⁷ Another possible mechanism is that it enhances endocannabinoid transmission

• **BACKGROUND:** Because pharmacological therapies may play an important role in managing musculoskeletal pain, the appropriate use of medicines for common conditions like low back pain (LBP) is critical. New evidence on the effects and safety of paracetamol, nonsteroidal anti-inflammatory drugs (NSAIDs), opioid analgesics, muscle relaxants, antibiotics, and antidepressants for LBP warrants an updated overview for musculoskeletal clinicians on this topic.

• **CLINICAL QUESTION:** How effective and safe are paracetamol, NSAIDs, opioid analgesics, muscle relaxants, antibiotics, and antidepressants compared with placebo for treating LBP?

• **KEY RESULTS:** For acute LBP (<12 weeks), muscle relaxants and NSAIDs may be superior to placebo for reducing pain, but the effects of opioids, antibiotics, and antidepressants are unknown. Paracetamol provides no additional benefit for acute LBP. For chronic LBP (>12 weeks), NSAIDs, antidepressants, and opioids may be

superior to placebo for reducing pain, but opioids have an established profile of harms. Antibiotics may also reduce pain for people with chronic LBP with Modic type 1 changes, although the risks may outweigh their benefits. The effects of paracetamol and muscle relaxants for chronic LBP were unclear.

• **CLINICAL APPLICATION:** NSAIDs may have a role in managing acute and chronic LBP, with cautious use in people who may be at greater risk of experiencing adverse events. Paracetamol, opioid analgesics, antibiotics, muscle relaxants, and antidepressants should only be prescribed following a discussion between the treating clinician and the patient, considering the risks and possible benefits, and after or in conjunction with recommended nonpharmacological strategies for improving LBP. *J Orthop Sports Phys Ther* 2022;52(7):425-431. Epub: 18 May 2022. doi:10.2519/jospt.2022.10788

• **KEY WORDS:** antibiotics, low back/lumbar spine, medications, pain, spinal stenosis

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and modulates descending serotonergic inhibitory pathways.³¹

Current Evidence of Benefits and Harms

Although paracetamol is generally considered safe when taken within the recommended dose limits (up to 4 g daily for a few days to several weeks), there are concerns about its long-term use at maximum therapeutic doses when treating chronic pain (>12 weeks),²⁹ for example, an increased risk of hepatotoxicity²¹ and gastrointestinal bleeding (hazard ratio = 1.20; 95% confidence interval [CI]: 1.03, 1.40) with high doses of paracetamol when taken for long durations, although at lower rates than with nonselective NSAIDs or combination use.^{28,37}

There is high-certainty evidence from 1 trial (n = 1652) that paracetamol (regular dosing of up to 4 g daily for up to 4 weeks) conferred no savings in time to recovery from pain than placebo for acute LBP (<12 weeks) in the immediate term (<2 weeks) (mean difference [MD], 1.5; 95% CI: -1.3, 4.3) on a 0-to-100 pain scale (TABLE 1).³⁵ A *when required* (as needed) dose regimen for up to 4 weeks similarly showed no benefit for either pain intensity or time to recovery in the immediate term (TABLE 1).³⁵

The effect of paracetamol does not change even with the people who comply with a prescribed treatment regime.³⁰ The number of participants reporting adverse events was similar across the treatment and placebo groups: 18.5% in the regular paracetamol group, 18.7% in the as-needed paracetamol group, and 18.5% in the placebo group.³⁵ There are no placebo-controlled clinical trials available on the effect of paracetamol for chronic LBP.

Nonsteroidal Anti-inflammatory Drugs

NSAIDs are prescribed with the aim of reducing inflammation and pain. NSAIDs are considered for patients with LBP and a suspected inflammatory component.²³ This includes clinical presentations of LBP with additional joint “stiffness and tightness” and/or the presence of inflammatory markers (eg, elevated C-reactive protein or tumor necrosis factor alpha).

Nonselective NSAIDs (eg, ibuprofen, naproxen, meloxicam, and diclofenac) reduce pain by inhibiting cyclooxygenase enzymes 1 and 2, whereas selective NSAIDs (eg, celecoxib) target cyclooxygenase enzyme 2.²³

Current Evidence of Benefits and Harms

The use of NSAIDs is recommended in practice guidelines of nonspecific LBP, but not specific pathology (eg, spinal stenosis).⁸ For nonspecific LBP, 14 out of 15 practice guidelines recommended NSAIDs, compared with 0 out of 4 for LBP from spinal stenosis.⁸ In a recent review, NSAIDs reduced pain by 7 points on a 0- to 100-point scale.²³ There was high-quality evidence that NSAIDs were not associated with increased risk of any adverse events (relative risk [RR] = 1.1; 95% CI: 1.0, 1.2) or serious adverse events (RR = 1.5; 95% CI: 0.4, 5.2) (TABLE 2).

NSAIDs may increase the risk for specific adverse events, such as gastrointestinal adverse events (odds ratio [OR] = 1.80-4.22) and heart failure (OR = 1.85-2.49), but the risk of stroke (OR = 0.97-1.18) and myocardial infarction (OR = 0.84-2.22) was uncertain.^{23,24} Some patient cohorts are at increased risk of adverse events if taking NSAIDs, such as those with cardiovascular and renal disease, pregnant women (first and third trimester), and those taking anticoagulants.²³

Opioids

Opioids are usually considered when non-opioid analgesics such as paracetamol (acetaminophen) and NSAIDs have not been effective or in addition to these medicines.³⁴ Opioids produce analgesia by their actions on the nervous system, particularly by inhibiting neurotransmitter release from the primary afferent terminals in the spinal cord and activating descending inhibitory controls in the midbrain.¹³

Opioid analgesics are commonly used for treating acute and chronic LBP, although there is significant concern about their use in this context.³³ Half of patients in the United States prescribed opioid

analgesics have chronic LBP.⁴ In Australia, half of the approximately 3.6 million general practice encounters for LBP in 2015-2016 resulted in opioid prescription.¹⁰ However, opioid prescription for LBP is common not only in primary care but also in tertiary care (hospital) settings.¹⁶ In 1 Australian study evaluating the care provided to patients presenting to the emergency department for LBP, 1767 (69.6%) of presentations received an opioid, with oxycodone being administered in 57% of these cases.¹⁶

Current Evidence of Benefits and Harms

The evidence for the effect of opioids compared with placebo in the context of acute LBP management is uncertain, with no trials available.² Adding opioids to NSAIDs is not superior to NSAIDs alone for treating acute LBP, with no additional pain relief or improvements in function.¹⁸

For chronic LBP, there is moderate-quality evidence from 13 studies (n = 3419) that opioids provide a 10-point reduction in pain (on a 0 [no pain] to 100 [worst pain imaginable] scale) in the short term (≤3 months) (TABLE 1).² In half of the trials, at least 50% of participants withdrew from the studies due to adverse events or perceived lack of effect. Common adverse events were gastrointestinal (eg, constipation, nausea, vomiting), central nervous system (eg, headache, somnolence, and dizziness), and autonomic (eg, dry mouth).² There was an overall higher risk of experiencing adverse events with opioid analgesics compared with placebo (RR = 1.3; *P* < .01). The median rate (interquartile range) of adverse events was 49.1% (44.0%-55.0%) for placebo and 68.9% (55.0%-85.0%) for opioids. Serious adverse events were at least twice as likely for people who received opioids, compared with placebo (OR = 2.22 [1.19-4.14]).³³

Similarly, for combination analgesics containing an opioid and a non-opioid analgesic, the benefits were small (<15 points on a 0- to 100-point scale). There was moderate evidence of pain relief in the intermediate term (≥3 months, <12 months

TABLE 1		OVERVIEW OF PAIN AND FUNCTION OUTCOMES FOR EACH MEDICATION COMPARED WITH CONTROL					
Medication	Scale ^a	Follow-up	Type	LBP Type	MD (95% CI)	Trials (n)	Quality of Evidence
<i>Pain</i>							
Paracetamol ^{1,33}	0-100	<2 weeks	Acetaminophen	Acute	1.5 (–1.3, 4.3)	1 (1520)	High
NSAIDs ²⁵	0-100	≤3 weeks	Nonselective NSAIDs	Acute	–7.3 (–11.0, –3.6)	4 (815)	Moderate
			Nonselective NSAIDs	Chronic	–6.0 (–11.0, –1.0)	4 (847)	Low
			Selective NSAIDs	Chronic	–9.1 (–13.6, –4.7)	2 (507)	Low
Opioids ²							
Single ingredient	0-100	≤3 months	Mix	Chronic	–10.1 (–12.8, –7.4)	13 (3419)	Moderate
Combination opioid and simple analgesic	0-100	≥3 months, <12 months	Tramadol plus paracetamol	Chronic	–11.9 (–19.3, –4.4)	2 (501)	Moderate
Muscle relaxants ¹²	0-100	≤2 weeks	Nonbenzodiazepine	Acute	–7.7 (–12.1, –3.3)	16 (4546)	Very low
			Benzodiazepine	Acute	2.0 (–9.8, 13.8)	1 (112)	Moderate
			Antispastic	Acute	–1.6 (–15.3, 12.1)	1 (103)	Low
		3 to 13 weeks	Nonbenzodiazepine	Acute	0.6 (–4.5, 5.7)	3 (612)	Moderate
			Benzodiazepine	Acute	–1.0 (–10.4, 8.4)	1 (103)	Low
			Antispastic	Acute	4.0 (–7.7, 15.7)	1 (99)	Moderate
			Antispastic	Chronic	–5.4 (–13.7, 2.9)	1 (80)	Very low
Antibiotics ^{6,11}	0-100	100 days	Amoxicillin/clavulanate	Chronic	–13.0 ^a	1 (144)	-
		12 months	Amoxicillin/clavulanate	Chronic	–26.0 ^a	1 (144)	-
		12 months	Amoxicillin	Chronic	–0.8 (–1.6, 0.0)	1 (180)	-
Antidepressants ¹⁷	0-100	10 days to 6 months	Mix	Chronic	–4.3 (–6.2, –2.5)	16 ^c	Low
<i>Function</i>							
Paracetamol ²⁷	0-100	<2 weeks	Acetaminophen	Acute	–1.9 (–4.8, 1.0)	1 (1652)	High
		>2 weeks to ≤3 months		Acute	0.4 (–1.7, 2.5)	1 (1652)	High
NSAIDs ^{16,38}	0-24	≤3 weeks	Selective NSAIDs	Acute	–2.0 (–2.9, –1.2)	2 (437)	High
		4 to 16 weeks	Mix	Chronic	–0.85 (–1.3, –0.4)	4 (1161)	Low
Opioids ²	0-100	2 weeks	Tramadol	Chronic	–6.3 (–12.2, –0.3)	1 (103)	Very low
Muscle relaxants ¹²	0-100	≤2 weeks	Nonbenzodiazepine	Acute	–3.3 (–7.3, 0.7)	7 (2438)	Very low
			Nonbenzodiazepine	Mixed	–19.2 (–27.7, –10.7)	1 (329)	Low
			Benzodiazepine	Acute	0.0 (–13.2, 13.2)	1 (112)	Low
		3 to 13 weeks	Antispastics	Acute	2.0 (–15.6, 19.6)	1 (103)	Low
			Nonbenzodiazepine	Acute	4.3 (–1.4, 10.1)	2 (422)	Moderate
			Benzodiazepine	Acute	–6.9 (–12.1, –1.7)	1 (103)	Moderate
			Antispastics	Chronic	–3.2 (–8.3, 1.8)	1 (80)	Very low
Antibiotics ^{6,11}	0-24	100 days	Amoxicillin/clavulanate	Chronic	–3.5 ^a	1 (144)	-
		12 months	Amoxicillin/clavulanate	Chronic	–7.0 ^a	1 (144)	-
		12 months	Amoxicillin	Chronic	–2.3 (–4.2, –0.4)	1 (180)	-
Antidepressants ¹⁷	0-100	10 days to 6 months	Mix	Chronic	–1.3 (–1.0, –1.6)	6 ^c	Low
<i>Abbreviations: CI, confidence interval; LBP, low back pain; MD, mean difference; NSAIDs, nonsteroidal anti-inflammatory drugs.</i>							
<i>^aMedian with no interquartile range provided. This was converted from a 0-to-10 to a 0-to-100 scale.</i>							
<i>^bRMQD 0 to 24, where higher scores indicate greater disability and pain.</i>							
<i>^cSample size not provided.</i>							
<i>Quality of evidence was extracted from the included studies.</i>							
<i>–No data.</i>							

following administration) with the combination of paracetamol and tramadol for chronic LBP (MD, –11.9; 95% CI: –19.3, –4.4).² The long-term effect of opioids in the context of LBP management was unclear. However, ongoing use of opioids is generally discouraged for chronic noncancer pain, as the benefits are often small and they have an established profile of harms.¹

TABLE 2

OVERVIEW OF HARMS FOR EACH MEDICATION

Medication	Outcome	Follow-up	Type	LBP Type	Result	Trials (n)	Quality of Evidence
<i>Pain</i>							
Paracetamol ^{1,27}	AE	<12 weeks	Acetaminophen	Acute	1.07 (0.86, 1.33)	1 (1624)	High
	Serious AE		Acetaminophen	Acute	0.90 (0.31, 2.67)	1 (1643)	Moderate
NSAIDs ²⁵	AE	All time points	Mix	Mix	RR 1.1 (1.0-1.2)	21 (5153)	High
	Serious AE	All time points	Mix	Mix	RR 1.5 (0.4-5.2)	2 (635)	Moderate
	GI AE	All time points	Mix	Mix	RR 2.5 (1.2-5.2)	3 (1167)	High
Opioids ^{2,37}	AE	All time points	Opioid	Mix	RR 1.30 (1.1-1.6)	5 (2213)	-
	AE	All time points	Opioid	Mix	68.9% (55%-85%) ^a	8 ^b	-
	Serious AE	All time points	Opioid	Mix	OR 2.22 (1.2-4.1)	8 (2558)	Moderate
Muscle relaxants ¹²	AE	All time points	Nonbenzodiazepine	Acute	RR 1.6 (1.2-2.0)	16 (3404)	Low
	Serious AE	All time points	Nonbenzodiazepine	Acute	RR 2.3 (0.3-20.8)	2 (830)	Very low
	AE	All time points	Antispastics	Acute	RR 2.0 (1.1-3.8)	2 (280)	Moderate
	AE	All time points	Benzodiazepine	Acute	RR 1.8 (0.9-3.6)	2 (159)	Low
Antibiotics ^{6,11}	AE	12 months	Amoxicillin/clavulanate	Chronic	65%	1 (77)	-
	Serious AE	12 months	Amoxicillin/clavulanate	Chronic	0%	1 (77)	-
	AE	12 months	Amoxicillin	Chronic	56%	1 (89)	-
	Serious AE	12 months	Amoxicillin	Chronic	7%	1 (89)	-
Antidepressants ¹⁷	AE	All time points	Mix	Chronic	OR 1.58 (1.28-1.93)	9 ^b	Low
	Serious AE	All time points	Mix	Chronic	OR 1.29 (0.56-2.94)	6 ^b	Very low

Abbreviations: AE, adverse event; GI, gastrointestinal; LBP, low back pain; NSAIDs, nonsteroidal anti-inflammatory drugs; OR, odds ratio; RR, risk ratio.

^aMedian rates with interquartile range.

^bSample size not provided.

-No data.

Risk of persistent use of opioids increases with each day of use.⁴ Twelve days' use of opioids is associated with a 24% risk of persistent use at 1 year, and 31 days' use is associated with an approximately 43% risk of persistent use at 1 year.⁴ Initiating long-acting opioid preparations is associated with greater risk of overdose (up to 6 times) and persistent use.⁴ Patients and prescribers should be aware of these risks before commencing treatment with opioid analgesics and only consider opioid medicines if non-opioid therapies have been tried and found to be insufficient. Given the increased risk of opioid-related overdose, benzodiazepines and opioids should not be co-prescribed.³²

There are currently no placebo-controlled trials evaluating the effect of opioids for acute LBP. However, there is 1 registered trial that will determine whether a long-acting formulation of oxycodo-

ne/naloxone is effective for the treatment of acute LBP.²²

Muscle Relaxants

Muscle relaxants (benzodiazepine and nonbenzodiazepine skeletal muscle relaxants) are often used to treat muscle pain and stiffness in people with LBP.¹⁴ Currently, there is no rigorous trial evidence to support the use of benzodiazepines (muscle relaxants with anxiolytic and sedative properties) in this context.¹² Furthermore, their sedative properties mean they are discordant with a key aspect of guideline-endorsed care: to stay active and avoid prolonged periods of bed rest.²⁵

Current Evidence of Benefits and Harms Until recently, it was considered that skeletal muscle relaxants provided clinically important pain relief (>15 points on a 0- to 100-point scale) for acute LBP, although their benefits for chronic LBP were uncertain.³ However, in a recent system-

atic review¹² involving both published and unpublished trials, the pooled effects from nonbenzodiazepine antispasmodics (eg, carisoprodol, tizanidine, cyclobenzaprine, thiocolchicoside, orphenadrine, methocarbamol, metaxalone) were associated with a very small reduction in pain intensity at 2 weeks or less (following administration) compared with control (placebo, continuation of usual care, waiting list, or no treatment) (MD, -7.7; 95% CI: -12.1, -3.3; 16 trials, 4546 participants). These findings are based on very low-certainty evidence, warranting further evidence from large, rigorous trials to ascertain the benefits of muscle relaxants for acute LBP.¹²

There was low-certainty evidence that the pooled effects from these nonbenzodiazepine antispasmodic muscle relaxants were associated with an increased risk of nonserious adverse events (RR = 1.6; 95% CI: 1.2, 2.0; 16 trials, 3404 participants) but not serious adverse events

(ie, those resulting in hospitalization or death) (RR = 2.3; 95% CI: 0.3, 20.8; 2 trials, 830 participants; very low-certainty evidence).¹²

There was no effect of nonbenzodiazepine muscle relaxants on disability for acute LBP.¹² However, there was moderate-quality evidence that benzodiazepines provided improvements in disability in the short term (3-13 weeks) of 7 points on a 0- to 100-point scale (95% CI: -12.1, -1.7; 1 trial, 103 participants).¹² The clinical relevance of these effects is questionable.

For mixed LBP, nonbenzodiazepine antispasmodics were associated with a reduction in disability in the immediate term (≤ 2 weeks; **TABLE 1**) compared with control (-19.2; -27.7, -10.7; 1 trial, 329 participants; low-certainty evidence).¹² For chronic LBP, there was very low-quality evidence that antispasmodics did not reduce disability at the 2-week follow-up or LBP in the short term (3-13 weeks after administration) (**TABLE 1**).¹²

Antibiotics

Unlike analgesic drug classes, antibiotics aim to treat an infection. Although the prevailing theory is that around 90% of LBP is from an unknown cause, some research had suggested that just under half of all nonspecific LBP may be due to infection.⁶ The presence of *Propionibacterium acnes* and *Corynebacterium propinquum* in the herniated lumbar discs of patients was argued as evidence.⁵ The theory was that following a disc herniation, the disc and vertebral endplate became infected, resulting in LBP. The presence of Modic type 1 changes (oedema within vertebral body) on imaging was cited as evidence for the infection.

Current Evidence of Benefits and Harms

Two randomized controlled trials assessed this theory in patients aged between 18 and 65 years, with back pain for over 6 months, magnetic resonance imaging evidence of disc herniation at any level between L3 and S1, and Modic type 1 changes. In Albert et al,⁶ patients were given 100 days of either a single dose or a double dose of placebo or amoxicillin/

clavulanate (500 mg/125 mg in the first trial and 750 mg⁶ of amoxicillin only in the second trial¹¹). In 2013,⁶ median LBP reduced in the antibiotics group from 6.7 (on a 0-to-10 scale) at baseline to 5.0 after 100 days and 3.7 by 1 year, whereas the placebo group remained at 6.3 from baseline to 1 year. In 2019,¹¹ for the Modic type 1 changes, mean LBP reduced in the antibiotics group from 6.5 at baseline to 4.5 by 1 year and, in the placebo group, from 6.3 at baseline to 5.2 at 1 year, with no results available at 100 days. A third RCT was registered in 2015 (ACTRN12615000958583) and is still ongoing.

The drug-related adverse event rates ranged from 56% to 65% (more detail in **TABLE 2**). If antibiotics are effective in reducing LBP, there would still remain health risks in prescribing 100 days of antibiotics, particularly with increasing awareness and concerns around antimicrobial resistance¹¹ and *Clostridioides difficile* infection.²⁶ The World Health Organization identified antibiotic resistance as 1 of the “biggest threats to global health” and has specifically advised health professionals to “only prescribe antibiotics according to clinical guidelines.”³⁶

Antidepressants

Antidepressants are a collection of medications that have been used in the treatment of LBP through a range of different proposed mechanisms.²⁰ Broadly, antidepressants are thought to benefit people with LBP through reduced pain, improved mood, and/or improved sleep.¹⁹

Current Evidence of Benefits and Harms

A recent review and meta-analysis on antidepressants for chronic LBP found low confidence that duloxetine, a selective serotonin-norepinephrine reuptake inhibitor, was more effective than placebo, with a reduction in pain of 4.33 (95% CI: 6.15, 2.50) on a 0-to-100 scale.¹⁷ There was also low confidence of a reduction in disability, with a reduction of 3.22 (95% CI: 4.96, 1.48) on a 0-to-100 scale. The reductions in pain and disability were not considered clinically significant.

Like other medications, using antidepressants also carries risks of harms. In 9 trials, there was low confidence that antidepressants increased the odds of experiencing an adverse effect (1.58; 95% CI: 1.28, 1.93). There was very low confidence that antidepressants did not result in higher odds of a serious adverse event (1.29; 95% CI: 0.56, 2.94). There were no studies completed on the effects of antidepressants for acute LBP.

SUMMARY

OF THE MEDICATION CATEGORIES DISCUSSED (opioids, paracetamol, NSAIDs, muscle relaxants, antibiotics, and antidepressants), only NSAIDs (selective and nonselective) showed benefits (when compared with placebo) in both acute and chronic LBP. Like paracetamol, opioids, muscle relaxants, antibiotics, and antidepressants, NSAIDs did however carry risks of harms in individuals with specific comorbidities (ie, kidney disease).

Despite the uncertainty around the benefits of medications (when compared with placebo) for LBP, they remain recommended in practice guidelines. In a 2018 systematic review, 15 existing practice guidelines for treating acute and chronic LBP were identified.²⁷ Of the 15 guidelines included in the 2018 review, 14 (93%) supported the use of NSAIDs for the treatment of acute and chronic LBP, 57% of the guidelines recommended paracetamol (50% for acute and 37% for chronic), 87% recommended opioids (61% for acute and 38% for chronic), 54% recommended muscle relaxants (50% for acute and 33% for chronic), and 80% recommended antidepressants. No guidelines made any recommendations for or against antibiotics for treating LBP.

Given the uncertain evidence of benefits (**TABLE 1**) and risk of harms (**TABLE 2**), practice guidelines may need to be updated to reflect the current evidence for each medication type. In general, medicines should not be used as the sole treatment for pain, but rather combined with safe,

nonpharmacological strategies to help reduce reliance on or use of the medicines. If any of the medicines discussed here are deemed appropriate in the specific circumstances of the individual, they should be used alongside guideline-endorsed nonpharmacological strategies such as superficial heat (eg, heat wrap therapy) and/or physical therapy (ie, exercise, education, and manual therapy) to assist with pain relief.¹⁵ A consideration of the individual's medical and medication history can also guide decision making regarding the appropriateness of these medicines.

Treatment effects reported in clinical trials and systematic reviews represent average effects and do not serve to predict individual treatment response. Therefore, the utility of these treatments should be discussed by the patient and the clinician, alongside a consideration of the cost, benefits, and harms.

CONCLUSION

NSAIDS MAY HAVE A ROLE IN THE management of LBP, with consideration given to the appropriateness of their use in people who may be at greater risk of experiencing adverse events from these medicines. Opioids, paracetamol, muscle relaxants, antibiotics, and antidepressants should only be prescribed following a discussion between the treating practitioner and the patient, considering the risks and possible benefits, and after or in conjunction with recommended nonpharmacological strategies for improving LBP. ●

KEY POINTS

FINDINGS: For acute LBP (<12 weeks), muscle relaxants and NSAIDs may be superior to placebo for reducing pain, but the effects of opioids, antibiotics, and antidepressants are unknown. For chronic LBP (>12 weeks), NSAIDs, certain antidepressants, and opioids may be superior to placebo for reducing pain, but opioids have an established profile of harms.

CLINICAL IMPLICATIONS: Medications should only be prescribed following a discussion between the treating clinician and patient, considering the risks, possible benefits, and after or in conjunction with recommended non-pharmacological strategies for improving LBP.

CAUTION: Future randomised controlled trials may result in changes to these recommendations.

STUDY DETAILS

AUTHOR CONTRIBUTIONS: Drs Anderson and Abdel Shaheed were responsible for the concept, drafting, and revision of the manuscript, with Dr Anderson as the guarantor.

DATA SHARING: The data included in this manuscript were extracted from the referenced studies.

PATIENT AND PUBLIC INVOLVEMENT: No patient or members of the public were involved in this manuscript.

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Focused Issue on Low Back Pain Clinical Research From Early Career Researchers: Delivering the Best Work From the Brightest Minds in Musculoskeletal Research to Help Clinicians Help Patients

Why Devote (Yet Another!) Journal Issue to Low Back Pain?

Low back pain (LBP) is the most disabling musculoskeletal condition in the world, and it is the first reason people choose to seek care from rehabilitation clinicians.³ Neck and back pain combined are the most important drivers of health care spending in the United States.⁵ Despite the well-known economic and societal burden, LBP is an underfunded research priority among (inter)national funding bodies. The absence of funding makes it challenging for researchers who focus their research efforts on LBP to secure funding for research projects, especially at the doctoral and postdoctoral levels.

Why the Focus on Early Career Researchers?

Early career researchers are often plagued with uncertainty about whether they can

continue their research. Therefore, the *Journal of Orthopaedic & Sports Physical Therapy* (JOSPT) is proud to dedicate this month's issue to LBP clinical research led by early career researchers. Eagle-eyed readers will notice the contributions of early career researchers: each article has an early career researcher as

first and last (senior) author—positions that signify leadership in conceiving of and conducting the research. The definition of early career researcher is contested. We required the papers vying for inclusion in the July issue to have leadership from researchers with no more than 5 years of experience after completing their doctoral degree.

Time to Embrace Diversity in LBP Clinical Research

Clinical research on LBP has historically focused on the adult population (18 to 60–70 years of age), predominantly in primary and secondary health care settings. This month's issue addresses 3 key elements of social determinants of health to address relevant research questions related to these newly emerging themes: (1) age, (2) setting, and (3) socioeconomic status.

Are you interested in the evidence for the clinical management of LBP in children and adolescents?⁹ Given the increasing focus on older adults in the LBP literature, would you like to know which of the 3 most frequently used

• **SYNOPSIS:** The July 2022 focused issue of the *Journal of Orthopaedic & Sports Physical Therapy* is dedicated to clinical research on low back pain (LBP), a societal and economic health problem that is often underfunded. In this issue, the contribution of early career researchers is substantial and, as a testament, each article has an early career researcher as first and last author. The issue includes 2 literature reviews, 3 research reports, 2 clinical commentaries and 1 viewpoint, addressing timely topics in the field of LBP including the diversity

of the LBP population under study, in terms of age, setting, and socioeconomic status. Moreover, methodological topics such as clinimetrics, causal mediation analysis, and evidence synthesis (systematic and narrative) are central to the issue. *J Orthop Sports Phys Ther* 2022;52(7):412–413. doi:10.2519/jospt.2022.11385

• **KEY WORDS:** clinical measurement (clinimetrics), low back/lumbar spine, pain, systematic review/meta-analysis

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patient-reported outcome measures for physical functioning performs better in older adults with LBP?⁶ A focus on LBP research in emergency departments has recently emerged in the literature, but what are estimates of recurrence of LBP in this setting and which prognostic factors are associated with pain recurrence?¹¹ Lately, more attention is given to more socioeconomically disadvantaged populations with LBP, but where do these disparities and inequalities intersect with the provision of care for patients with LBP?¹⁰

Better Research Methods to Better Capture Complexity and Mechanisms of Interventions

Defining “what” and “how” to measure outcomes in patients with LBP is an essential prerequisite to capturing the most relevant health aspects to this population. While these aspects of measurement have been extensively studied for patients with nonspecific LBP,² it remains unknown what are the most frequently used outcome domains and measurement instruments in clinical trials with patients with specific causes of LBP, such as lumbar spinal stenosis.⁴ The number of mediation analysis studies in the field is growing rapidly, and psychosocial factors are often important mediators of treatment effects.⁸ Joyce et al provide answers as to whether, in a randomized controlled trial setting, the effects of yoga or physical therapy are mediated by psychological mechanisms.⁷

Evidence Syntheses to Educate Patients and Clinicians on the Most Effective Care

Individual patient education has a pivotal role when managing LBP, but what are its effects on the most relevant outcomes (ie, pain intensity and physical functioning) in patients with (sub)acute LBP?¹² At the same time, although not prescribing pain medications, rehabilitation clinicians and patients should know which medications

are the most effective for LBP. A clinical commentary summarizes the most recent evidence on this topic, adding considerations that are relevant for practicing clinicians.¹

High-Quality Clinical Research with Implications for Daily Practice

Thank you to all the authors who contributed to this focused issue on LBP. We present an issue with a broad focus that addresses timely and specific research questions. We hope that JOSPT readers will find useful information and practical points to apply to their daily work helping patients manage LBP. Enjoy reading! ●

STUDY DETAILS

AUTHOR CONTRIBUTIONS: Both authors conceived the content of this manuscript together. Alessandro Chiarotto drafted the first version of this manuscript; Hopin Lee commented for substantial intellectual revision. Both authors approved the submission of this manuscript.

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Roland-Morris Disability Questionnaire, Oswestry Disability Index, and Quebec Back Pain Disability Scale: Which Has Superior Measurement Properties in Older Adults With Low Back Pain?

There is a high prevalence of low back pain (LBP) in older adults¹¹—a musculoskeletal problem that is not well understood^{26,41} or treated. Given multiple factors (eg, psychological and physical comorbidities, maladaptive coping, and age-related physical

problems) can modify the LBP experience in older adults.^{47,50}

Physical function is a core outcome domain for patients with LBP.^{6,24,43,51} International consensus recommends using the Roland-Morris Disability Questionnaire (RMDQ) or the Oswestry Disability Index (ODI) to measure physical function in clinical trials.⁵ They are the most frequently used patient-reported outcome measures (PROMs) for physical function in the adult population.¹⁹ Another common measure is the Quebec Back Pain Disability Scale (QBPDS),⁴ which has promising measurement properties.⁸

A measurement instrument needs adequate measurement properties (ie, validity, reliability, and responsiveness).³⁰ Instruments must be evaluated in head-to-head studies, where they are administered to the same target population, in the same setting, at the same time points, and with the same comparator instruments.⁷ In recent systematic reviews of head-to-head comparisons, there was no single instrument (RMDQ, ODI, or

● **OBJECTIVE:** To examine the validity, reliability, and responsiveness of 3 commonly used questionnaires for assessing physical function (ie, Oswestry Disability Index [ODI], Quebec Back Pain Disability Scale [QBPDS], and Roland-Morris Disability Questionnaire [RMDQ]) in older patients undergoing chiropractic care for low back pain (LBP).

● **DESIGN:** Head-to-head clinimetric comparison.

● **METHODS:** Patients completed the ODI, QBPDS, and RMDQ at baseline and after 2 weeks of treatment. Reliability was evaluated for internal consistency (Cronbach α), test-retest reliability (interclass correlation coefficient [ICC]), and measurement error (standard error of measurement and smallest detectable change [SDC]). Structural validity was evaluated through unidimensional confirmatory factor analysis, and construct validity was investigated by a priori hypotheses with other measures. Responsiveness was evaluated by testing a priori hypotheses using data at baseline and at 2-week follow-up.

● **RESULTS:** Two hundred fourteen patients (53% males and 47% females) with a mean age

of 66.2 years (standard deviation = 7.8 years) were included, of which 193 patients completed the 2-week follow-up for our responsiveness analysis. The RMDQ, ODI, and QBPDS showed sufficient internal consistency (Cronbach α of .89, .86, and .94, respectively) and test-retest reliability (ICC[2,1] of 0.85, 0.89, and 0.84, respectively). The SDC for the RMDQ was 6.9, for the ODI was 19.1, and for the QBPDS was 23.6, which are values larger than the minimal important change. None of the measures met all criteria for sufficient structural validity, but the RMDQ and ODI exhibited a partial unidimensional fit. The questionnaires had sufficient construct validity and responsiveness.

● **CONCLUSION:** The ODI, QBPDS, and RMDQ have similar measurement properties in older adults with LBP. *J Orthop Sports Phys Ther* 2022;52(7):457-469. Epub: 18 May 2022. doi:10.2519/jospt.2022.10802

● **KEY WORDS:** anatomy/spine, clinical measurement (clinimetrics), low back/lumbar spine, manual therapy/spine, outcome measures

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QBPDS) that came out on top in terms of measurement properties.^{7,32} All failed in some key measurement aspects⁸: issues with the unidimensionality of the total score (which is routinely used) and with measurement error (measured as the smallest detectable change [SDC]), which is usually larger than 20% of the score range.^{7,8,44}

Few studies have focused on the measurement properties of the RMDQ, ODI, and QBPDS in older adults (older than 65 years) with LBP. Hicks and Manal²¹ found sufficient test-retest reliability and convergent/construct validity of the ODI and QBPDS in older adults but did not evaluate responsiveness. Davidson and Keating¹⁰ examined reliability and responsiveness in older adults with LBP but did not evaluate validity. Additionally, the sample sizes were too small to draw any firm conclusion.¹⁰ Most importantly, no single study evaluated a head-to-head analysis in the 3 domains of validity, reliability, and responsiveness.

We aimed to compare the validity, reliability, and responsiveness of the RMDQ, ODI, and QBPDS in older adults with LBP in a head-to-head clinimetric comparison.

METHODS

THIS CLINIMETRIC STUDY USED DATA from a prospective observational study²⁶ with measurements at baseline and after 2 weeks. Chiropractors from The Netherlands Chiropractic Association were asked to participate. The chiropractors who agreed were spread across the Netherlands and recruited patients from their practices between September 2018 and December 2019. Patients who called the practices to book an appointment and who met the inclusion criteria were invited to participate.

The data are part of a larger international cohort of the Back Complaints in the Elders – Chiropractic (BACE-C)²⁶ study. Patients were eligible if they were aged 55 years or older, had LBP (with or without leg symptoms), and had not

seen a chiropractor in the previous 6 months. LBP was defined as pain from the thoracolumbar 12th rib junction to the first sacral vertebrae, including pelvic pain and pain referred to the leg. Exclusion criteria were as follows: inadequate command of the Dutch language and no Internet access via a computer, tablet, or smartphone. We excluded people with a cognitive disorder and those with suspected tumor, fracture, infection, or any other potential red flag or condition considered a contraindication for spinal manipulation therapy. The ethics committee of the VU University Medical Center approved the study protocol (2017-618). All patients gave online informed consent to participate in the study.

Data Collection

A link to the questionnaire was e-mailed to patients and completed as a web-based questionnaire at baseline and after 2 weeks. A 2-week time interval was chosen for follow-up based on previous research,^{7,18} as we expected little change within a 2-week period, and it would capture more patients as stable. During baseline and 2-week data collection, participants received chiropractic care based on the chiropractor's pragmatic treatment plan. Patients received treatment at least once a week, and frequency varied between once and 3 times a week. We did not record the duration of treatment or the specifics of what each treatment consisted of as the chiropractor was free to treat based on clinical need.

Baseline questionnaires captured the following: (1) sociodemographic characteristics (eg, age, sex, marital status), (2) physical activity (measured with the International Physical Activity Questionnaire [IPAQ]),² (3) LBP information including an 11-point numeric rating scale to measure pain intensity as well as items on duration of pain and onset and previous episodes of LBP, (4) the Dutch version of the 3 physical functioning PROMs (ie, 24-item RMDQ,^{3,37} ODI Version 2.1a,^{16,48} and QBPDS^{28,42}), (5) health-related qual-

ity of life measured with the EQ-5D-5L (EuroQol 5 Dimension 5 Level),⁴⁹ (6) comorbidities using the Self-Administered Comorbidity Questionnaire,⁴⁵ and (7) the STarT Back Screening Tool.⁴⁰

At the 2-week follow-up, a 7-point "global change" scale was included with the questionnaires. Participants rated the extent to which their back problem had changed from the start of treatment. The rating scale had 7 response options: 1 = a lot better, 2 = much better, 3 = better, 4 = a little better, 5 = about the same, 6 = a little worse, and 7 = much worse. All 3 PROMs, the IPAQ, and the EQ-5D-5L questionnaires were completed at the 2-week follow up.

Physical Functioning PROMs

The 24-item RMDQ^{21,37} was developed in 1983 using and modifying items from the Sickness Impact Profile. It consists of 24 items that represent activities routinely done or avoided that are likely affected by LBP. A 0-to-24 sum score is calculated by counting the number of endorsed items,³⁷ with higher scores indicating worse function. The RMDQ score used a modified proportional recalculation method¹⁹ to deal with missing data. The online version of the RMDQ was a forced submission; there were no missing data.

The ODI Version 1.0^{16,48} was first published in 1980 as an indicator of disability (defined as the limitation of a patient's performance compared with that of a fit person). The ODI consists of 10 items representing different health constructs. The sum of the section scores is divided by the total possible score (50 if all sections are completed), and the total is multiplied by 100 to yield a percentage score. We used the ODI Version 2.1a.³⁶ Missing data from the ODI were considered in the total score calculation by removing the question from the total score and recalculating the total score based on completed items.

The QBPDS^{28,42} was published in 1995. It provided a scale based on a conceptual model via interviews with patients using item response theory.²⁷ The authors aimed

to develop a scale that was sufficiently informative over a wide range of disability levels and responsive.²⁸ The total score is calculated by adding the 20 individual item scores; each item score ranges from 0 to 5, and the total score ranges from 0 to 100. The online version of the QBPDS was a forced submission; there were no missing data.

In all 3 PROMs, a lower score after baseline indicated better physical function.

Measurement Properties and Statistical Methods

The Consensus-based Standards for the selection of health Measurement INstruments (COSMIN) taxonomy³⁰ was used to define the measurement properties under investigation. Statistical analyses were performed using SPSS Version 26. Mplus Version 8.4 was used for the confirmatory factor analysis.

Structural and Construct Validity

To evaluate structural validity, a confirmatory factor analysis for a single-factor solution^{17,20,48,52} was performed considering that the total scores of these questionnaires are routinely used. To evaluate model fit and unidimensionality, the comparative fit index (CFI), Tucker-Lewis index (TLI), root-mean-square error of approximation (RMSEA), and standardized root-mean-square residual (SRMR) were used. Guidelines²³ suggest that a CFI and TLI of 0.95 or higher, an RMSEA close to or below 0.06, and an SRMR close to 0.08 or higher represent good fitting models. An instrument was deemed to have better structural validity if it fulfilled all these criteria.

Construct validity was evaluated by testing 7 a priori specified hypotheses (TABLE 1). These hypotheses were formulated based on previous research^{9,29,31} as well as discussion and agreement among 4 researchers (A.J., T.H., S.M.R., and A.C.). For sufficient construct validity, an instrument was required to meet at least 75% of these hypotheses.³⁴ The rationale for the hypothesis is presented in TABLE 1.

Reliability

Reliability was evaluated by testing (1) internal consistency, (2) test-retest reliability, and (3) measurement error.

The Cronbach α was used as a parameter of internal consistency based on the total score. A Cronbach α coefficient greater than or equal to .70 and less than .95 is regarded as satisfactory.³⁴ The Cronbach α if item deleted was also calculated.

Test-retest reliability was explored in the subgroup of patients identified post hoc as stable based on self-reporting of their condition as “a little better,” “about the same,” or “a little worse” on the 7-point global change scale. Interclass correlation coefficients for agreement ($ICC_{\text{agreement}}$) were calculated for each instrument. A PROM was considered to have better test-retest reliability if displaying an $ICC_{\text{agreement}}$ greater than or equal to 0.70 or an $ICC_{\text{agreement}}$ of at least 0.10 higher than another PROM.³⁰ A sensitivity analysis categorizing “a little better” as stable was also explored to confirm the robustness of the results.

We defined measurement error by calculating the SDC, which was $SEM \times 1.96 \times \sqrt{2}$. First, we calculated the standard error of measurement (SEM) for agreement and then the error associated with repeated measures to identify the SDC. A PROM had sufficient measurement error if the SDC was less than the minimal important change (MIC).³⁴ The MIC values proposed by Ostelo et al³³ were used to assess this measurement property (ie, 5 for the RMDQ, 10 for the ODI, and 20 for the QBPDS) (TABLE 5). Percent in scale range (RMDQ, 28.6; ODI, 19.1; QBPDS, 23.6) was calculated by dividing the SDC by the total range score of the instrument and converting it into a percentage.

Responsiveness

We examined the ability of the RMDQ, ODI, and QBPDS to detect change over 2 weeks. Five hypotheses (TABLE 1) were formulated regarding expected mean differences between change scores of the

instruments, on expected correlations between changes in scores on the instruments. The hypotheses were formulated based upon previous research^{9,29,31} and consensus. Standardized mean responses were calculated by dividing mean change scores by the respective standard deviations (SDs) of the change. The area under the curve (AUC) was calculated as the probability of correctly discriminating patients as stable or unchanged. An AUC greater than 0.70 and close to 0.94 was considered sufficient.³⁴ Acceptable responsiveness requires that more than 75% of the hypotheses be confirmed³⁴ (TABLE 1).

RESULTS

A TOTAL OF 286 PATIENTS WERE ELIGIBLE for the study, of which 214 (75%) patients agreed to participate and completed the baseline questionnaire. There were 193 (90%) patients who completed follow-up measures at 2 weeks. The mean age at baseline was 66 years (SD = 7.8), 47% were female, and the median duration of LBP was 214 days (interquartile range, 2 days to 31 years) (TABLE 2). The mean score at baseline of the RMDQ was 9.8 (SD = 5.5) (score, 0-24) or 41 on a 100-point scale, the ODI was 23.0 (SD = 16.3) (score, 0-100), and the QBPDS was 31.6 (SD = 17.6) (score, 0-100).

A group of participants who did not wish to participate in the follow-up measurements completed a paper version of the baseline questionnaire. The baseline descriptive variables were similar in both those who participated and those who did not participate in the follow-up measurements (age, 70 [8.2], [57-83]; 47% females, 53% males; body mass index, 28.3 [6.5]), indicating no selection bias. Electronic versions of physical functioning are adequate for clinical and research settings for assessing patients with chronic LBP.¹

We classified 110 (51%) patients as “Not Stable” and 83 (39%) as “Stable” (TABLE 3). Twenty-one (10%) respondents

TABLE 1

A PRIORI HYPOTHESES TO ASSESS RMDQ, ODI, AND QBPDS CONSTRUCT VALIDITY AND RESPONSIVENESS IN OLDER PATIENTS WITH CHRONIC LOW BACK PAIN (N = 193)

Hypotheses for Construct Validity ^a	RMDQ		ODI		QBPDS	
1. Demographic						
The mean score (standard deviation) of the back-specific PROMs in people aged >75 is higher than the mean score of the back-specific PROMs in people aged <75.	>75 9.9 (5.5)	<75 6.5 (5.1)	>75 22.7 (16.5)	<75 15.8 (14.6)	>75 31.8 (179)	<75 21.9 (16.5)
https://doi.org/10.1111/j.1526-4637.2003.03042.x	Confirmed +		Confirmed +		Confirmed +	
2. The mean score (standard deviation) of the back-specific PROMs in people with lower education is higher than the mean score of the back-specific PROMs in people with higher education.	↓ Educ 8.7 (0.57)	↑ Educ 8.0 (0.53)	Educ 23.1 (1.7)	Educ 19.2 (1.6)	Educ 30.3 (1.8)	Educ 26.4 (1.7)
https://doi.org/10.1186/1471-2474-15-255	Confirmed +		Confirmed +		Confirmed +	
3. Physical Tests						
The mean score (standard deviation) of the back-specific PROMs in people walking less than 200 m is higher than the mean score of the back-specific PROMs in people walking more than 200 m.	<200 m 13.3 (4.7)	>200 m 7.3 (4.4)	<200 m 37.7 (17.5)	>200 m 16.8 (11.9)	<200 m 45.0 (14)	>200 m 24.1 (13.8)
https://dx.doi.org/10.3390%2Fjcm9041023	Confirmed +		Confirmed +		Confirmed +	
4. Pain						
The correlation between the back-specific PROMs and the NRS pain scale is at least 0.1 higher than the correlation between the back-specific PROMs and the EQ-5D-5L anxiety domain.	NRS 0.44	EQ-5D-5L 0.26	NRS 0.41	EQ-5D-5L 0.22	NRS 0.41	EQ-5D-5L 0.23
http://dx.doi.org/10.1016/j.spinee.2012.10.030	Confirmed +		Confirmed +		Confirmed +	
5. Quality of Life						
The correlation between the back-specific PROMs and the EQ-5D-5L mobility subscale is 0.2 higher than the correlation between the back-specific PROMs and the EQ-5D-5L anxiety subscale.	Mobility 0.57	Anxiety 0.26	Mobility 0.56	Anxiety 0.22	Mobility 0.53	Anxiety 0.23
http://dx.doi.org/10.1016/j.spinee.2012.10.030	Confirmed +		Confirmed +		Confirmed +	
6. Physical Activity						
The mean score (standard deviation) of the back-specific PROMs in people with expected decrease in activity over the next 3 months is higher than the mean score of the back-specific PROMs in people with no expected decrease in activity over the next 3 months.	<Activity 10.6 (5.3)	Activity 8.4 (5.2)	<Activity 24.1 (16)	Activity 21.3 (17.1)	<Activity 33.4 (18)	Activity 28.2 (16.4)
https://dx.doi.org/10.3390%2Fjcm9041023	Confirmed +		Confirmed +		Confirmed +	
7. Worrysome						
The correlation between the back-specific PROMs and the StarT Back Tool score is 0.2 higher than the correlation between the back-specific PROMs and the StarT Back distress subscale.	StarT 0.63	Distress 0.53	StarT 0.61	Distress 0.53	StarT 0.46	Distress 0.42
http://dx.doi.org/10.1136/bmjopen-2016-012445	Not confirmed –		Not confirmed –		Not confirmed –	
Number That Met Hypotheses (%)	83%		83%		83%	

Table continues on next page.

TABLE 1

A PRIORI HYPOTHESES TO ASSESS RMDQ, ODI, AND QBPDS CONSTRUCT VALIDITY AND RESPONSIVENESS IN OLDER PATIENTS WITH CHRONIC LOW BACK PAIN (N = 193) (CONTINUED)

Hypotheses for Responsiveness ^a		RMDQ		ODI		QBPDS	
1.	The correlation of the change scores on the back-specific PROMs with the change scores on the NRS pain scale is 0.2 higher than the correlation of the change scores on the back-specific PROMs with the STarT Back Tool distress subscale high-risk group. http://dx.doi.org/10.1136/bmjopen-2016-012445	NRS 0.43 ^b	Distress 0.18 ^b	NRS 0.34 ^b	Distress 0.3 ^b	NRS 0.42 ^b	Distress 0.09 ^b
		Confirmed +		Not confirmed –		Confirmed +	
2.	The correlation of the change scores of the back-specific PROMs and the NRS change scores is 0.2 higher than the correlation of the change scores of the back-specific PROMs and IPAQ change scores. https://doi.org/10.1590/S1980-6574201700020015	NRS 0.35 ^b	IPAQ –0.08	NRS 0.29 ^b	IPAQ 0.04	NRS 0.39 ^b	IPAQ –0.02
		Confirmed +		Confirmed +		Confirmed +	
3.	The standardized mean response (standard deviation) of the back-specific PROMs in patients categorized with acute low back pain (<6 weeks) is larger than the standardized mean response of the back-specific PROMs in patients categorized with chronic low back pain (>12 weeks). http://dx.doi.org/10.6061/clinics/2019e789	Acute 8.6 (4.7)	Chronic 7.6 (5.0)	Acute 20.4 (13.5)	Chronic 21.3 (15.5)	Acute 28.5 (14.2)	Chronic 26.2(16.8)
		Confirmed +		Not confirmed –		Confirmed +	
4.	The standardized mean response (standard deviation) of the back-specific PROMs in patients categorized as “improved” on the GPE is at least larger than the standardized mean response of the back-specific PROMs in patients categorized as “not improved” on the GPE. https://doi.org/10.1093/ageing/afw127	Improved 7.5 (4.7)	Not improved 8.4 (4.8)	Improved 17.1 (12.3)	Not improved 20.4 (15.2)	Improved 24.1 (14.5)	Not improved 28.2 (15.7)
		Confirmed +		Confirmed +		Confirmed +	
5.	The area under the curve is higher than 0.70 for the change scores of the PROMs in patients categorized as “improved” on the GPE. Number That Met Hypotheses (%)	0.75 Confirmed + 100%		0.72 Confirmed + 80%		0.75 Confirmed + 100%	
Abbreviations: Educ, education; EQ-5D-5L, EuroQol 5 Dimension 5 Level; GPE, Global Perceived Effect scale; IPAQ, International Physical Activity Questionnaire; NRS, numeric rating scale; ODI, Oswestry Disability Index; PROMs, patient-reported outcome measures; QBPDS, Quebec Back Pain Disability Scale; RMDQ, Roland-Morris Disability Questionnaire.							
^a The DOIs provided are research supporting the hypothesis.							
^b Correlations were statistically significant: P<.000.							

did not answer the 7-point global change follow-up question.

Validity

Confirmatory factor analysis (TABLE 4) suggested that the 1-factor solution did not adequately fit the QBPDS (CFI, 0.88; TLI, 0.87; RMSEA, 0.18; SRMR, 0.09). There was a partial fit for the RMDQ (CFI, 0.93; TLI, 0.93; RMSEA, 0.06; SRMR, 0.12) and the ODI (CFI, 0.96; TLI, 0.95; RM-

SEA, 0.07; SRMR, 0.06). The ODI had 9 missing iterations due to many patients skipping question 8 (asking about LBP during sex). The RMDQ and QBPDS had no missing iterations. A confirmatory factor analysis was performed for 23 of 24 questions of the RMDQ. Question 24 was not discriminative enough as all participants responded “no” to the question “I stay in bed most of the time because of my back.”

The results of hypothesis testing indicated that all 3 questionnaires had sufficient construct validity—met at least 75% of the hypotheses (TABLE 1).

Reliability

Cronbach α values at baseline for the RMDQ (.89), ODI (.86), and QBPDS (.94) indicated sufficient internal consistency. Item deletion had no change in the results of the Cronbach α (APPENDIX).

TABLE 2

BASELINE DESCRIPTIVES

	Baseline	2 Weeks	Excluded Participants (Baseline Only)	Missing at Baseline
Demographic data	n = 214	n = 193	n = 21	
Age , mean (SD) [IQR], years	66.2 (7.8) [55-96]	66.3 (7.8) [55-96]	65.3 (7.5) [55-78]	0 (0%)
Sex				
Female, n (%)	100 (47%)	94 (47%)	8 (50%)	0 (0%)
Male, n (%)	114 (53%)	107 (53%)	8 (50%)	0 (0%)
Body mass index , mean (SD)	26.2 (4.2)	26.2 (4.3)	28.7 (5.6)	0 (0%)
Lifestyle factors				
Physical activity , median (range), min/week	660 (0-1980)	668 (0-1860)	583 (0-960)	
Smoker				
Yes, n (%)	24 (11%)	19 (9%)	2 (13%)	
No, n (%)	171 (80%)	167 (83%)	12 (75%)	19 (9%)
Alcohol consumption				
Never, n (%)	26 (12%)	25 (12%)	1 (6%)	
1-3× per month, n (%)	106 (50%)	99 (49%)	10 (62%)	
4× or more per month, n (%)	63 (29%)	62 (31%)	3 (19%)	19 (9%)
Back pain with sleeping				
Never, n (%)	56 (27%)	55 (26%)	5 (32%)	
<1-2× per week, n (%)	101 (47%)	99 (73%)	2 (12%)	
3× per week or more, n (%)	52 (24%)	57 (27%)	9 (56%)	5 (2%)
Sociodemographics				
Ethnicity, n (%), Dutch	204 (95%)	196 (97%)	16 (100%)	0 (0%)
Marital status				
Single, n (%)	29 (14%)	29 (14%)		
Married, n (%)	178 (83%)	165 (82%)	16 (100%)	
Living apart together, n (%)	7 (3%)	7 (4%)		0 (0%)
Level of education				
Low, n (%)	33 (15%)	30 (15%)	4 (25%)	
Middle, n (%)	100 (46%)	95 (47%)	10 (62%)	
High, n (%)	81 (38%)	76 (38%)	2 (13%)	0 (0%)
Employment status				
At work, n (%)	77 (36%)	72 (36%)	7 (49%)	
Not at work, n (%)	137 (65%)	125 (62%)	7 (49%)	0 (0%)
Nature and severity of LBP				
Combined pain scores at this moment, mean (SD)	5.5 (2.2)	5.5 (2.2)	10.9 (12.1)	0 (0%)
Combined pain scores this past week, mean (SD)	5.9 (2.2)	6.0 (2.1)	6.0 (2.5)	0 (0%)
Combined pain scores at this moment in your leg, mean (SD)	4.3 (2.5)	4.3 (2.5)	5.8 (2.5)	0 (0%)
Combined pain scores this past week in your leg, mean (SD)	5.4 (2.4)	4.5 (9.9)	5.9 (2.4)	0 (0%)
Previous episode				
Yes, n (%)	173 (81%)	143 (81%)	12 (75%)	
No, n (%)	41 (19%)	38 (19%)	4 (25%)	0 (0%)
Started with a bad movement , n (%)	45 (21%)	40 (20%)	5 (31%)	
Started with heavy lifting , n (%)	12 (6%)	10 (5%)		
Accident/trauma , n (%)	9 (4%)	8 (4%)		
Start slowly over days , n (%)	36 (17%)	35 (17%)	4 (25%)	

Table continues on next page.

TABLE 2

BASELINE DESCRIPTIVES (CONTINUED)

	Baseline	2 Weeks	Excluded Participants (Baseline Only)	Missing at Baseline
Other* , n (%)	112 (52%)	108 (54%)	7 (44%)	1 (1%)
Duration of low back pain , n = mean # days (IQR)	51 (4-279)			
Frequency of low back pain				
<1× per week, n (%)	19 (9%)	16 (8%)	3 (19%)	
1× per week, n (%)	4 (2%)	2 (1%)	1 (6%)	
Every day, n (%)	171 (80%)	165 (82%)	7 (44%)	
Every minute of the day, n (%)	20 (9%)	18 (9%)	5 (31%)	0 (0%)
Pain referral to leg				
Yes, n (%)	125 (58%)	115 (57%)	13 (81%)	
No, n (%)	87 (41%)	84 (42%)	3 (19%)	0 (0%)
Numbness or tingling in leg or foot				
None-mild, n (%)	169 (92%)	161 (80%)	8 (50%)	
Moderate-very severe, n (%)	44 (8%)	67 (33%)	8 (50%)	0 (0%)
Weak or heavy feeling in leg or foot				
None-mild, n (%)	152 (71%)			
Moderate-very severe, n (%)	62 (29%)			0 (0%)
Average max walking in the last week				
More than 3 km, n (%)	97 (46%)	91 (45%)	6 (38%)	
200 m-3 km, n (%)	89 (42%)	84 (42%)	6 (38%)	
15 m-200 m, n (%)	22 (10%)	20 (10%)	4 (24%)	
Less than 15 m, n (%)	6 (3%)	6 (3%)		0 (0%)
Present episode of pain				
Comes and goes, n (%)	124 (58%)	115 (57%)	6 (38%)	
Constant, n (%)	90 (42%)	86 (43%)	10 (62%)	0 (0%)
Expectations of treatment				
Recovery/improvement, n (%)	200 (94%)	193 (96%)	14 (88%)	
Stay about the same, n (%)	11 (5%)	7 (4%)	2 (12%)	2 (1%)
Expectations of recovery after 3 months				
Pain free, n (%)	59 (28%)	53 (26%)	8 (50%)	
Large improvement, n (%)	137 (64%)	134 (66%)	4 (25%)	
About the same, n (%)	18 (8%)	14 (7%)	4 (25%)	13 (6%)
Expectations of work/activity in next 3 months				
Fully recovered, n (%)	92 (43%)	90 (45%)	8 (50%)	
Partially recovered, n (%)	23 (11%)	21 (10%)	4 (25%)	
About the same, n (%)	21 (10%)	20 (10%)	4 (25%)	
Not applicable, n (%)	76 (36%)	69 (34%)		2 (1%)
Had to live rest of life with pain				
Very dissatisfied, n (%)	72 (34%)	68 (34%)	10 (63%)	
Dissatisfied, n (%)	81 (38%)	80 (40%)	1 (6%)	
Not satisfied or dissatisfied, n (%)	49 (23%)	42 (21%)	4 (25%)	
Satisfied, n (%)	12 (6%)	11 (5%)	1 (6%)	13 (6%)
Recovered from pain since it started				
Recovered, n (%)	99 (45%)	94 (47%)	7 (44%)	
Not recovered, n (%)	115 (55%)	107 (53%)	9 (56%)	13 (6%)

Table continues on next page.

TABLE 2

BASELINE DESCRIPTIVES (CONTINUED)

	Baseline	2 Weeks	Excluded Participants (Baseline Only)	Missing at Baseline
Previous treatment of low back pain				
Yes, n (%)	151 (71%)	145 (72%)	11 (69%)	
No, n (%)	63 (29%)	56 (28%)	5 (31%)	0 (0%)
Functional status				
RMDQ sum score, baseline, mean (SD)	9.5 (5.6)	9.6 (5.4)	11.3 (6.3)	0 (0%)
RMDQ sum score, 2 weeks, mean (SD)		6.5 (5.2)		0 (0%)
ODI sum score, baseline, mean (SD)	23.3 (16.5)	22.8 (16.5)	21.1 (16.7)	0 (0%)
ODI sum score, 2 weeks, mean (SD)		15.4 (14.7)		0 (0%)
QBPDS sum score, baseline, mean (SD)	31.3 (17.6)	31.0 (17.4)	32.7 (17.7)	0 (0%)
QBPDS sum score, 2 weeks, mean (SD)		22.1 (16.6)		0 (0%)
Comorbidities				
Heart, n (%)	24 (11%)	21 (10%)	2 (13%)	
High blood pressure, n (%)	48 (22%)	47 (23%)	3 (19%)	
Lung, n (%)	13 (6%)	13 (6%)	1 (6%)	
Diabetes, n (%)	15 (7%)	14 (7%)	4 (25%)	
Stomach, n (%)	11 (5%)	11 (5%)	2 (13%)	
Kidney, n (%)	7 (3%)	34 (17%)	3 (19%)	
Liver, n (%)	4 (1%)	4 (2%)	0 (0%)	
Blood conditions, n (%)	7 (3%)	6 (3%)	1 (6%)	
Cancer, n (%)	10 (5%)	7 (4%)	0 (0%)	
Depression, n (%)	10 (5%)	9 (5%)	0 (0%)	
Arthritis hip/knee, n (%)	49 (23%)	48 (24%)	5 (31%)	
Arthritis hand, n (%)	31 (14%)	31 (15%)	1 (6%)	
Rheumatoid arthritis, n (%)	14 (6%)	11 (55%)	1 (6%)	
Neck/shoulder problems, n (%)	96 (45%)	116 (57%)	9 (56%)	
Headache/migraine, n (%)	27 (12%)	27 (13%)	3 (19%)	
Foot problems, n (%)	48 (22%)	43 (21%)	3 (19%)	
Gout, n (%)	15 (7%)	12 (6%)	1 (6%)	
Neurological conditions (MS/Parkinson, etc), n (%)	9 (4%)	8 (4%)	0 (0%)	
Other, n (%)	17 (8%)	18 (9%)	0 (0%)	
Quality of life				
EQ-5D-5L score	0.70 (0.23)	0.71 (0.21)	0.54 (0.36)	0 (0%)
EQ-5D-5L VAS score	70.2 (16.4)	71 (16.1)	61.1 (18.2)	0 (0%)
StarT Back				
Worrying thoughts about LBP, n (%)	3.42 (2.05)	3.33 (2.0)	4.56 (2.4)	0 (0%)
Bothersomeness, moderately-extremely, n (%)	1.24 (1.34)	1.16 (1.3)	2.13 (1.7)	0 (0%)

Abbreviations: EQ-5D-5L, EuroQol 5 Dimension 5 Level; IQR, interquartile range; LBP, low back pain; MS, multiple sclerosis; n, number of participants; ODI, Oswestry Disability Index; QBPDS, Quebec Back Pain Disability Scale; RMDQ, Roland-Morris Disability Questionnaire; SD, standard deviation; VAS, visual analog scale.

The results of the test-retest reliability showed sufficient reliability as ICC_{agreement} values exceeded 0.70: RMDQ, ICC(2,1) = 0.87 (95% confidence interval [CI]: 0.75, 0.94); ODI, ICC(2,1) = 0.94 (95% CI: 0.88, 0.97); QBPDS, ICC(2,1) = 0.95 (95%

CI: 0.91, 0.98). The SDC (TABLE 5) was insufficient for all 3 instruments (RMDQ, 6.9 [30% in scale range]; ODI, 19.1 [18% in scale range]; and QBPDS, 23.6 [17% in scale range]); these are larger than previous MIC range values.³³

Responsiveness

Responsiveness of the RMDQ, ODI, and QBPDS was tested in 193 patients. AUC values for the RMDQ of 0.75 (standard error [SE], 0.04; 95% CI: 0.68, 0.82), ODI of 0.72 (SE, 0.04; 95% CI: 0.64, 0.79), and

TABLE 3

STABLE VS NON-STABLE PATIENTS

GPE:	Participants Classified as "Stable" (n = 83)						Participants Classified as "Not Stable" (n = 110)					
	Baseline		Follow-up		Difference		Baseline		Follow-up		Difference	
	X	SD	X	SD	X	SD	X	SD	X	SD	X	SD
Questionnaire												
Roland-Morris Disability Questionnaire	9.9	6.1	4.8	4.9	5.1	1.2	9.2	5.3	7.8	5	1.4	0.3
Oswestry Disability Index	24.2	16.3	10.6	11.9	13.6	4.4	22.2	16.8	19	15.5	3.2	1.3
Quebec Back Pain Disability Scale	32.8	18.2	16.5	15.1	16.3	3.1	30.3	17.5	26.4	16.3	3.9	1.2
GPE:	Participants Classified as "Stable" (n = 83)						Participants Classified as "Not Stable" (n = 109)					
	Baseline		Follow-up		Difference		Baseline		Follow-up		Difference	
	X	SD	X	SD	X	SD	X	SD	X	SD	X	SD
Questionnaire												
Roland-Morris Disability Questionnaire	9.9	6.1	4.7	4.9	5.2	1.2	9.1	5.3	7.8	5	1.3	0.3
Oswestry Disability Index	24.4	16.3	10.6	11.9	13.8	4.4	22.1	16.8	18.7	15.2	3.4	1.6
Quebec Back Pain Disability Scale	33	18.1	16.3	15.1	16.7	3	30.2	17.6	26.3	16.3	3.9	1.3
GPE:	Participants Classified as "Stable" (n = 155)						Participants Classified as "Not Stable" (n = 37)					
	Baseline		Follow-up		Difference		Baseline		Follow-up		Difference	
	X	SD	X	SD	X	SD	X	SD	X	SD	X	SD
Questionnaire												
Roland-Morris Disability Questionnaire	9.5	5.6	6.1	5	3.4	0.6	9.5	5.9	8.4	5.3	1.1	0.6
Oswestry Disability Index	22.4	16.1	13.2	12.5	9.2	3.6	25.8	18.2	24.6	19.1	1.2	-0.9
Quebec Back Pain Disability Scale	28.3	18.3	20	15.5	8.3	2.8	32	15.5	31.5	17.5	0.5	-2
Abbreviations: GPE, Global Perceived Effect scale; SD, standard deviation.												
Improved = A lot improved, Much improved; Not improved = A little improved, About the same, A little worse, Much worse, A lot worse												

QBPDS of 0.75 (SE, 0.04; 95% CI: 0.67, 0.82) were obtained (APPENDIX).

Results of the a priori hypothesis tests on questionnaire responsiveness are presented in TABLE 1. All 3 PROMs confirmed the responsiveness of the instruments, meeting the 75% threshold.

A sensitivity analysis of categorizing the 7-point global change scale "a little better" answer as "Stable" instead of "Not

Stable" showed an improvement in sensitivity of the SDC values (APPENDIX).

DISCUSSION

WE EVALUATED THE RELIABILITY, validity, and responsiveness of the RMDQ,²¹ ODI,⁴⁸ and QBPDS⁴² in older adults with LBP. The questionnaires have sufficient construct validity, internal

consistency, test-retest reliability, and responsiveness. None of the instruments had sufficient unidimensionality for the total score following confirmatory factor analysis, with the ODI and RMDQ performing slightly better than the QBPDS. Overall, the RMDQ and ODI had superior measurement properties in older adults with LBP than the QBPDS.

Validity

We tested validity in 2 ways. First, we tested structural validity using confirmatory factor analysis. We found that the ODI and RMDQ had a better fit than the QBPDS.²³ Second, we tested construct validity using hypotheses that were defined a priori.⁴⁶ The construct validity of the 3 PROMs was supported by confirming 5 out of 7 (75%) of the predefined hypotheses, indicating sufficient performance.

When testing construct validity, it is important to test the construct with both

TABLE 4

CONFIRMATORY FACTOR ANALYSIS

	Model	χ^2	df	RMSEA	SRMR	90% CI	CFI	TLI
RMDQ	1 factor	2701.3*	230	0.057	0.121	0.048-0.067	0.934	0.927
ODI	1 factor	931.6*	45	0.068	0.0588	0.044-0.091	0.961	0.95
QBPDS	1 factor	10620.5*	170	0.153	0.088	0.174-0.192	0.883	0.869

Abbreviations: CFI, comparative fit index; CI, confidence interval; df, degrees of freedom; ODI, Oswestry Disability Index; QBPDS, Quebec Back Pain Disability Scale; RMDQ, Roland-Morris Disability Questionnaire; RMSEA, root-mean-square error of approximation; SRMR, standardized root-mean-square residual; TLI, Tucker-Lewis index.

* $P < .05$.

TEST-RETEST RELIABILITY

	Test										Retest										% in Scale Range		
	Cronbach α Internal Consistency										ICC Test-Retest												
	n	Min	Max	Mean	SD	SE	SE (.70-.95)	n	Min	Max	Mean	SD	SE	Mean Diff	Mean Diff SD	SRM	ICC >0.70	ICC 95% CIs	Var	SEM		SDC	MIC
Roland-Morris Disability Questionnaire	214	0	24	9.5	5.6	0.38	.89	193	0	21	6.5	5.2	0.37	3.3	4.86	0.68	0.85	0.76	6.134	2.48	6.87	5	28.60
Oswestry Disability Index	214	0	70	23.3	16.6	1.13	.86	192	0	62	15.4	14.5	1.06	77	13.51	0.57	0.89	0.82	47.51	6.89	19.11	10	19.11
Quebec Back Pain Disability Scale	214	1	100	31.3	17.6	1.2	.94	193	0	79	22.1	16.6	1.19	9.4	15.94	0.59	0.84	0.76	72.37	8.51	23.58	20	23.58

Abbreviations: CIs, confidence intervals; Diff, difference; ICC, interclass correlation coefficient; Mac, maximum; MIC, minimal important change; Min, minimum; n, number of participants; SD, standard deviation; SDC, smallest detectable change; SE, standard error; SEM, Standardized Response Mean; Var, Variance

related and unrelated constructs. We tested constructs from demographics, pain, physical activity, and worrisomeness. However, we could not evaluate content validity³⁴ as the original design²⁶ of the study did not collect qualitative data. A previous systematic review highlighted the need to evaluate this property of these instruments,⁵ and a head-to-head content validity study including older adults with LBP is needed. All 3 PROMs were designed for patients aged between 18 and 65 years and may not represent the physical function of the older adult. Further research on content validity in the older adult will help determine if these PROMs are appropriate for the older adult.

Reliability and Internal Consistency

The test-retest reliability results are consistent with other studies,^{7,10} and values did not change with item deletion or diminish internal consistency. Due to the insufficient structural validity especially with the QBPDS, the Cronbach α should be interpreted with caution. The reliability of the Dutch RMDQ was similar to that (0.89) in a study with a longer follow-up period (9 weeks).¹⁵ The ODI has similar reliability.³⁹ The QBPDS ICC value was similar to that of 0.93 reported in the original reliability study by Kopec et al.²⁸ The ICC value alone does not provide enough information about reliability, as the ICC is a relative reliability measure.¹⁴ Therefore, we also calculated an absolute reliability parameter, ie, the SDC for the 3 questionnaires, which is also an estimate of measurement error. The smaller the SDC, the more free the instrument is from measurement error.¹² For instance, the SDC value of 6.9 calculated for 14 days indicates that, for a specific patient, a change of more than 7 points is most likely due to true change in the functional disability status of that patient rather than measurement error.³³

Reliability and Measurement Error

The QBPDS, RMDQ, and ODI had excessive measurement error, as all 3 PROMs did not fall within the consensus-based MIC values.³³ Although the absolute

value of the QBPDS SDC was higher than the RMDQ and ODI, the proposed cutoff value was close to the range identified in previous work.³³ Nevertheless, MIC values of back-specific questionnaires fluctuate, depending on various features (eg, baseline scores, validity of the anchor).¹¹ It may be challenging for the instruments to disentangle the difference between “real” change (ie, change beyond measurement error) and “important” change, considering that the latter may fall within the range of the SDC. Therefore, we considered a change score to be minimally important only if it exceeded the SDC. SDC values can also be translated into the percentage of the scale range, and the SDC of the QBPDS would still be the smaller, equaling 17% of the 0-to-80 range, while 18% of the 0-to-100 range for the ODI and 29% of the 0-to-24 range for the RMDQ. Although similar in percentage, the QBPDS, RMDQ, and ODI displayed excessive measurement error,⁷ as all 3 PROMs did not fall within the consensus-based MIC values.³³ There are no studies on the MIC of these instruments in older adults, and future studies should fill this gap.

Responsiveness

The responsiveness of the PROMs as indicated by the AUC values is similar to the sensitivity of the PROMs in other studies.^{7,35} A previous systematic review on head-to-head comparison studies on the responsiveness of the ODI and RMDQ had already shown that these 2 instruments have fairly similar responsiveness.⁷ On the other hand, similar head-to-head data including the QBPDS were missing.

Limitations

We used a 2-week interval to measure the test-retest reliability of the questionnaires. Although a 2-week interval is not uncommon in previous validation studies³ of the physical function questionnaires, collecting data for a longer time frame could minimize an underestimate of the functional status scale's ability to show change (ie, lower change correlations, SRMs than studies with longer du-

ration). A second limitation may be the limited number of comparative measures at follow-up. We collected a broad range of baseline questionnaires that were not collected at 2-week follow-up and other follow-up time points in the BACE-C study as to not overwhelm the patients with questionnaires. In hindsight, collecting a few more pain questions could have added more hypothesis data to evaluate responsiveness more comprehensively.

Although we detected no differences in participants who completed the online questionnaires as opposed to those who completed the paper version, we do not rule out the possibility that an older group of patients chose not to participate because they are limited in their computer literacy. However, the demographics of the patients included in our study are consistent with an earlier descriptive study conducted in The Netherlands.³⁸

Chiropractors who participated volunteered their time and received continuing education points. Our results may reflect those practices that focus more on evidence-based practice,²⁵ which may compromise the generalizability of these findings. Lastly, we did not collect data on content validity, and given that all 3 questionnaires failed at some measure of validity, reliability, and responsiveness, it would be beneficial to evaluate content validity in future studies.

CONCLUSION

THE RMDQ, ODI, AND QBPDS HAVE sufficient internal consistency, test-retest reliability, construct validity, and responsiveness in an older adult clinical population with LBP. The 3 instruments have similar measurement properties, but other head-to-head clinimetric studies in older adults with LBP are needed, especially in assessing content validity. ●

KEY POINTS

FINDINGS: The Roland-Morris Disability Questionnaire (RMDQ), Oswestry Disability Index (ODI), and Quebec Back

Pain Disability Scale have sufficient validity, reliability, and responsiveness in older adults with low back pain (LBP).

IMPLICATIONS: The RMDQ and ODI should be used to evaluate physical function in older adults with LBP.

CAUTION: Content validity has not yet been assessed in older adults with LBP and is a priority to confirm the validity of the 3 patient-reported outcome measures in the older adult.

STUDY DETAILS

AUTHOR CONTRIBUTIONS: Drs Jenks, Chiarotto, Hoekstra, Ostelo, and Rubinstein were involved in study concept and design. All authors were involved in the drafting of the manuscript, critical revision of the article for important intellectual content, and final approval of the article.

DATA SHARING: Data sharing is not applicable to this article as no data sets were generated or analyzed during the current study.

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What Works When Treating Children and Adolescents With Low Back Pain?

Low back pain is a common health condition for all ages and responsible for significant individual, social, and economic burdens worldwide.¹⁸ One quarter to a third of children report persistent pain, including low back pain,⁵⁰ and up to 10% have some degree of disability.^{27,32,47} The years lived with disability due to low back pain increases with the age.¹⁶ Low back pain ranks sixth of all conditions for children aged 5 to 14 years and fourth for 10- to 24-year-olds.¹⁵ Point prevalence of low back pain among children and adolescents is 12%, lifetime prevalence is around 40%,²⁷ and annual incidence is approximately 15%.²⁷ Adolescents with persistent low back pain are about 4 times more likely to develop low back pain in

adulthood.²² Despite the link between low back pain in childhood and adulthood, there are important clinical differences between children and adults that have implications for diagnosis and management.

While low back pain is usually classified as nonspecific in adults (not

attributable to a recognizable specific pathology),¹⁸ identifiable anatomical causes for low back pain may be more common in children and adolescents.^{5,19} Scheuermann's disease (which can be associated with pain but more commonly presents as a permanent painless kyphosis of unknown etiology)⁵ and pars interarticularis stress fractures are prevalent in children and adolescents who present with low back pain.¹⁹ Other less common causes include seronegative spondyloarthropathies (eg, ankylosing spondylitis), intervertebral disc disease, tumors, and discitis. Identifying red flags, including night pain, weight loss, arthralgia (eg, heat, redness, edema), pain/stiffness in the morning, bony tenderness, and neurological signs and symptoms, is important to exclude serious spinal pathology in children and adolescents who present with low back pain.^{2,13} We do not address diagnosis and management of these specific pathologies in this Clinical Commentary.

Clinical Question: What Works for Children and Adolescents with Low Back Pain?

Children and adolescents have been overlooked in health research generally and back pain research specifically.³⁹ For a long time, low back pain in patients under 20 years of age was considered a red flag for serious spinal pathology.^{3,25,45} Research

• **BACKGROUND:** Low back pain is a common health condition for all ages. One quarter to a third of children report persistent pain, including low back pain.

• **CLINICAL QUESTION:** The aim of this Clinical Commentary is to provide an overview of evidence-based treatment approaches for children and adolescents with low back pain.

• **KEY RESULTS:** Physical, psychological, and pharmacological interventions are effective in reducing pain intensity and disability. Interdisciplinary and patient- and family-centered treatment approaches are the gold standard for persistent pain in children and adolescents. Communication between health professionals, children, and parents is a key part of a therapeutic alliance. The use of holistic and complementary therapies is not supported by compelling evidence.

• **CLINICAL APPLICATION:** Physical interventions can be delivered alone or as a component of other interventions. The interventions are delivered over 8 to 12 weeks. Psychological therapies are mostly delivered as a component of a multidisciplinary treatment program: cognitive behavioral therapy is most often used, and interventions usually run from 4 to 10 weeks. Pharmacological interventions should be delivered in combination with physical and psychological interventions. Tailor family-centered interventions to personal aspects, such as age, gender, and family structure. When communicating with children and adolescents, use simple language that is clear and direct. Aim to support trust between health professionals and parents to facilitate family decision making. *J Orthop Sports Phys Ther* 2022;52(7):419-424. Epub: 18 May 2022. doi:10.2519/jospt.2022.10768

• **KEY WORDS:** adolescent, biopsychosocial, child, exercise, interdisciplinary communication, low back pain

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into treatment approaches in children is sparse, and guideline recommendations are based on research in adults.^{3,25,45} However, low back pain in children and adolescents has gained more attention recently.^{26,31,48} Children and adolescents may have different biopsychosocial factors that contribute to the development of low back pain than adults: childhood and adolescence is a period of maturation of the musculoskeletal system, hormonal changes, and growth in cognitive and emotional relationships. It is unclear how these affect the onset and natural history of low back pain.

Children and adolescents may respond differently to interventions (eg, due to ability to understand behavior change techniques, different adherence to active interventions, and different social-cultural context). Effective treatment approaches may be unique to this population. We aim to provide a clear and concise overview of the available evidence for clinical practice. We do not address issues such as certainty of evidence and effect size and recognize that some depth and nuance is lost in preparing this summary. Our goal is to provide a simple overview of evidence-based treatment approaches for low back pain in children and adolescents.

Physical Interventions

What Does the Evidence Say? Physical interventions are effective for treating low back pain in children and adolescents.^{12,27,30} Physical interventions may reduce pain and disability at posttreatment compared to usual or active medical care, but effect sizes are uncertain.¹² It is also uncertain whether effects are sustained.¹² Combined physical and educational interventions could be effective in reducing pain intensity compared to home exercises or no treatment.²⁷ However, systematic reviews about physical interventions are based on a few studies with high risk of bias and low to very low certainty of evidence.^{12,27,30}

Clinical Application Physical interventions focus on promoting independence, return to functioning, and improving self-

efficacy in children and adolescents.¹⁷ For this reason, physical interventions are recommended ahead of passive interventions (eg, massage, electrotherapy).^{17,28} There are a range of physical intervention options, such as general exercise, aerobics, yoga, stretching, strengthening, and hydrotherapy.⁵⁰ Physical interventions can be delivered alone or as a component of broader treatment approaches.⁵⁰ The mode of delivery, supervised or home program, does not seem to impact the size of the effect, but efforts to support adherence are likely important.^{30,50}

The best type of intervention will likely depend on patient preferences and the expertise of the therapist. Consider varying the settings (eg, in the gym, at home, with or without equipment, in public settings) to increase the exercise skills.¹⁷ Previous experience with the type of intervention and the patient's ongoing pain report during the intervention should be considered.^{31,42} Make playful and interactive interventions a priority, as adherence is likely to be low if patients find the intervention boring.⁵⁰ Recommendations for dose and duration are conflicting with tested interventions delivered 1 to 2 times per week, with session duration between 20 and 45 minutes for 8 to 12 weeks.³⁰ Graded exposure to activities through gradually increasing intensity can help promote behavioral management.^{9,17,21} Some caution is necessary regarding recommendations due to very low certainty of the evidence of effect.

Psychological Interventions

What Does the Evidence Say? Treatment approaches for persistent pain based on the biopsychosocial model are recommended.^{43,50} Psychological interventions that aim to support healthy thoughts, beliefs, or behavioral responses can have important benefits for children and adolescents with persistent pain.^{11,43,50} A recent systematic review showed that psychological interventions slightly reduce pain intensity compared to active medical care, usual care, or waiting list.¹² Psychological interventions may result

in a slight reduction of functional disability and increase global impression of change sustained over the long term.¹² There is moderate to very low certainty of evidence that psychological therapies should be used in clinical practice for children and adolescents.¹² Pain neuroscience education may be complementary to psychological interventions.⁴¹ Understanding pain mechanisms decreases its threat value and leads to more effective pain coping strategies, which can help children and adolescents with persistent pain to develop self-efficacy and self-management skills.¹⁷

Clinical Application Psychological therapies focus on self-managing pain and disability.¹⁷ They are mostly delivered as a component of a multidisciplinary treatment program, typically with physical interventions.^{10,17,35} Cognitive therapies (eg, hypnosis, stress management, coping skills) and behavioral therapies (eg, relaxation training, biofeedback, graded exposure) have been used for children and adolescents.^{11,35} Cognitive behavioral therapy (CBT), a combination of these 2 types of interventions, is commonly used to promote improvements in pain and catastrophizing in adolescents with persistent pain.^{17,20} Pain neuroscience education can provide children and parents clear explanations about the nature of pain, typical course, differences between acute and persistent pain, explanations of brain processing in pain, and the influence of psychosocial factors in the pain experience.^{17,41}

The choice of specific intervention will depend on patient preference and the experience of the health professional. The mode of delivery, face-to-face or remote, does not seem to have a strong influence.^{30,50} For CBT, the intervention may range in quantity and content of modules and total duration. Modules can include components such as exposure, graded activity, pain education, relaxation, and recognition of emotions.¹⁰ The duration of the intervention usually ranges from 4 to 10 weeks depending on scope of the content.¹⁰ Caution should be applied to

these recommendations due to the low certainty of the evidence of effectiveness and sparse evidence regarding adverse effects.

Pharmacological Interventions

What Does the Evidence Say? Pharmacological interventions are often delivered to children and adolescents with persistent pain.¹² However, current evidence suggests that pharmacological interventions should not be delivered as a stand-alone intervention.^{12,13} A recent systematic review showed moderate evidence that pharmacological interventions, compared to placebo or other pharmacological interventions, likely reduce pain intensity, but this effect was not sustained long term.¹² It is necessary to exercise caution with pharmacological interventions. In summary, there is no high-quality evidence for the use of any pharmacological intervention in children and adolescents.⁷ This is due to lack of data and the barriers to conducting clinical trials of pharmacological interventions in this population.⁷

Clinical Application Only anticonvulsants (pregabalin) reduced pain intensity at posttreatment. Even though paracetamol is 1 of the most used medications for musculoskeletal pain in children and adolescents, there are limited data for its effect on pain relief.^{1,12} Antidepressants or nonsteroidal anti-inflammatory drugs (ie, ibuprofen) showed no benefit for pain reduction. Pharmacological interventions should be used in combination with physical and psychological interventions.¹² Opioids do not have long-term efficacy for persistent pain in children and adolescents and have a poor safety profile.¹³ Opioids should only be prescribed by specialist providers, with careful assessment of the benefits and risks.⁵¹

Holistic and Complementary Therapies

What Does the Evidence Say? Holistic and complementary therapies are usually provided in conjunction with conventional treatment. Among the options for holistic and complementary

therapies, acupuncture, massage, and relaxation techniques have been used in children and adolescents, but evidence for the effectiveness for children and adolescents with persistent pain is scarce.^{17,24,46}

A systematic review reported that acupuncture and hypnosis can have a positive effect on pain management in children; however, most of the evidence comes from procedure-related pain or pain in newborns.²⁴ A few studies have shown that massage, hypnosis, and relaxation techniques may be beneficial for persistent pain in children.^{6,23,24,44} However, the evidence base is small, and methodological quality of the studies is low—there is considerable uncertainty regarding effectiveness.

Clinical Application There is insufficient evidence of effectiveness and no evidence regarding adverse effects for holistic or complementary therapies. The evidence base is insufficient to justify recommending using these treatments for children with back pain.

Interdisciplinary and Family-Centered Approaches

What Does the Evidence Say? An interdisciplinary approach is the gold standard for persistent pain in children and adolescents.^{12,14,43,50} This approach is characterized by collaboration among health professionals who work closely and discuss treatment goals together.^{17,21,34} The treatment approach needs to be considered in a group and not in isolation by each therapist. An interdisciplinary approach for persistent pain in children and adolescents was effective in reducing pain intensity, pain-related disability, and symptoms of depression, and the benefits were maintained.²¹

Treatment approaches for children and adolescents should be patient and family centered.^{43,50} Parenting children and adolescents with persistent pain impacts family life.³⁷ Parents report anxiety, depressive symptoms, and parental role stress associated with the persistent pain in their children.³⁸ Furthermore,

there is a pathway correlating the parents' perception and behaviors regarding pain and the painful experiences of the children and adolescents.^{4,13,29,36,38,49} Family-focused approaches can be beneficial.⁸ For this reason, it is important to involve the whole family in the process of decision making, but this does not necessarily give parents the power of decision. Children and adolescents should have autonomy appropriate to their developmental stage and age, as self-efficacy and autonomy may be necessary for achieving goals and behaviors around health.³⁹ Furthermore, patient preferences for interventions must be considered and discussed.³⁹

Clinical Application The appropriateness of interdisciplinary intervention might be assessed through initially developing treatment goals through a shared process including children, parents, and a health professional.⁵⁰ Understanding these goals will help identify whether involving other health professionals is necessary. Usually, an interdisciplinary approach requires at least 3 health professionals working together, with interventions ranging from 1 to 3 times per week.²¹ This approach can be costly in terms of time and resources and may not be feasible for some families or in low- and middle-income countries.

Tailor family-centered interventions to personal aspects, such as age, gender, family structure, educational level, socioeconomic level, and psychological symptoms.^{43,50} Assessing the characteristics of the family can help. Assessments from more than 1 family member could be necessary, as family relationships are often too complex to be understood from 1 perspective alone.³⁶ Multidimensional pain instruments could be useful for this assessment since they assess various aspects of the pain experience (eg, intensity, duration, physical and psychological aspects).³¹ Spending some time to understand the family's routine will allow the therapist to better tailor the intervention to meet the patient's and the family's needs.

Communication Is Key to the Treatment Success

What Does the Evidence Say? Communicating with children according to their developmental stage and communicating with parents to build confidence can be challenging.^{31,40} Communication between health professionals, children, and parents is a key part of the therapeutic alliance, and it is directly associated with intervention adherence.⁴² Children and adolescents may feel insecure and afraid to talk about their problems or feelings with health professionals,⁴² and it is important to give space for discussion about causes, prognosis, risk factors, beliefs, potential impacts of the patient's condition, and available treatments. A shared decision-making framework offers a model to simplify communication between clinicians and patients.⁴²

Clinical Application Communication with children and adolescents needs to be clear, direct, and as simple as possible.⁴² Avoid technical and complex language as it is disempowering; tailor information delivery to the cognition level.⁴² Younger children are commonly underestimated in relation to health literacy, while adolescents are overestimated and receive an excess of complex information beyond their processing capacity.⁴² It is the clinician's responsibility to deliver information in a way that is understood by the patient. It is important that the professional validates the child's experience of pain and aligns treatment expectations.¹³ In some cases, pain will not disappear but can decrease sufficiently to enable life activities to return to normal. It could be helpful to explain that the 4 S's—sports, socialization, sleep, and school—can return to normal before pain disappears or decreases.¹³

There is a need for transparency and trust between health professionals and parents. Parents feel safer receiving as much information as possible about their children's condition.^{42,50} Parents directly influence the treatment of their children; excessive parental attention to pain or disability contributes to catastrophizing of pain in children.^{13,33} This means it may

be necessary to teach parents to focus on their child's function rather than on the disability caused by pain.¹³ Reinforce that parents' experience of pain and disability is different from the child's experience.¹³ Establishing a good relationship between the 3 stakeholders (ie, health professionals, children, and parents) facilitates family decision making, which is supported by honesty; trust; and discussion about the risks, benefits, and treatment options.⁴²

SUMMARY AND IMPLICATIONS

LOW BACK PAIN IN CHILDREN AND ADOLESCENTS is prevalent and needs to be appropriately managed. Physical, psychological, and pharmacological interventions, particularly delivered in combination, are effective for reducing pain intensity and improving disability. The effectiveness of other interventions, including holistic and complementary therapies, is uncertain.

Despite the fact that interventions recommended for managing low back pain in children are similar to those recommended to adults, clinicians must also consider the context, meaning, communication, and delivery mode that could influence treatment success. Aim for a biopsychosocial patient- and family-centered intervention tailored to age and cognition. When communicating with children and adolescents, use clear, direct, and simple language; avoid technical and complex language. A trust relationship between health professionals, children, and parents facilitates family decision making and supports intervention adherence. We recognize that there is a dearth of high-quality evidence to guide treatment decisions for these patients and hope ongoing and future research will add to the evidence base. ●

KEY POINTS

FINDINGS: Physical, psychological, and pharmacological interventions, delivered in combination, are effective for

persistent low back pain in children and adolescents.

IMPLICATIONS: Children and adolescents are not little adults. Clinicians need to consider the age, cognition, and family dynamics when tailoring interventions.

CAUTION: There is a lack of high-quality evidence to guide treatment decisions for children and adolescents, and it is expected that future research will add to the evidence base.

STUDY DETAILS

AUTHOR CONTRIBUTIONS: All authors were involved in the conception and design of the manuscript. Ms Leite and Dr Yamato drafted the manuscript, and all authors revised and approved the final version. All authors take responsibility for the integrity of the data and the accuracy of the manuscript.

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Delivering Value Through Equitable Care for Low Back Pain: A Renewed Call to Action

In 2003, the National Academy of Medicine (formerly Institute of Medicine) in the United States highlighted serious racial and ethnic disparities in musculoskeletal pain management.¹² Yet, 2 decades later, society is a long way from achieving equitable pain care. For example, guideline-adherent care is provided at a lower rate for Black and Hispanic patients with low back pain (LBP)¹⁵ compared to White patients and for people from low- compared to high-socioeconomic status neighborhoods.⁹

Disparate health outcomes experienced by different racial and ethnic groups during the COVID-19 pandemic have laid bare the inequities in health care systems and societies. As a result, people are demanding action to improve equity across all aspects of health care, including for musculoskeletal pain. Equity is the “absence of avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically” (TABLE).²⁴ Avoidable differences in pain management are exemplified by significantly different rates of analgesic prescription¹⁸ and use of rehabilitation³ for pain across various racial

and ethnic groups, even after accounting for socioeconomic status, health insurance, and general health status.¹⁵

Striving for equitable LBP care is rooted in providing just and ethical treatment for all people. But equity is more than simply providing better care for patients. Equitable care has critical implications for the growth and sustainability of the physical therapy profession. We assert that disparities in care due to unaddressed social determinants of health (SDOH) (which include factors such as education, social and built environment, culture, and economic stability), implicit provider biases, and structural characteristics of the health care system that hinder equitable care represent some of the greatest threats to delivering high-value physical therapy.

In this Viewpoint, we focus on LBP as 1 example of a musculoskeletal health condition. LBP is often the most common condition treated by physical therapists. LBP clinical practice guidelines increasingly and strongly support physical therapists as preferred first-contact providers. Physical therapists are ideally positioned to mitigate avoidable escalation of care, opioid use, and high costs associated with mismanagement of LBP, and data show significant inequities in LBP care across health care settings, including primary care¹⁶ and in the emergency department.²¹ We aim to increase awareness of equity as a key component of value in physical therapy, discuss factors that perpetuate disparate care, and highlight steps physical therapists can take to improve equitable LBP care.

Linking Equitable Care and Value

In a 2013 “call to action,” Jewell et al¹³ put forth a physical therapy value proposition: that physical therapists impart value through “*reduction of disability and improvement in health status of individuals and populations through more cost-effective physical therapist service delivery.*” Inequitable care jeopardizes physical therapists’ ability to consistently deliver on key features of this proposition. One key feature is the ability of physical therapists to provide a caring, patient-centered therapeutic relationship. Implicit ethnic, racial, gender, and other biases—which contribute to inequitable care—can erode

• **SYNOPSIS:** Equitable care for low back pain (LBP) is key to ensuring the value and sustainability of services delivered by physical therapists. In this Viewpoint, we discuss how social determinants of health, implicit provider biases, structural characteristics of the health care system, and health care policies contribute to disparate care for many individuals with LBP. We aim to increase awareness of equity as a key component of value in physical therapy and highlight steps physical

therapists can take to improve equitable LBP care. This “call to action” underscores the need to study, demonstrate, and advance equitable care for LBP by physical therapists to improve outcomes for patients and ensure the growth and sustainability of the physical therapy profession. *J Orthop Sports Phys Ther* 2022;52(7):414-418. Epub: 17 May 2022. doi:10.2519/jospt.2022.10815

• **KEY WORDS:** disparities, health care administration, pain, population health, psychology

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TABLE	DESCRIPTION OF KEY TERMS
Term	Description
Health disparity ^a	Differences in health outcomes or status (medical condition) among defined groups of people (ie, based on race/ethnicity, sex, education, or socioeconomic status).
Health equity ^b	Attainment of the highest level of health for all people. An important aspect of health equity is providing the necessary resources and services given individual differences and circumstances.
Implicit bias ^c	Unconscious behaviors exhibited by health care professionals that may influence clinical decision making and often stem from patient characteristics (ie, based on race/ethnicity, sex, education, or socioeconomic status).
Structural racism ^d	The complex interactions of strategies on a large scale that produce and perpetuate inequities in terms of access to care, services, and opportunities within society for racial minorities.
Social determinants of health ^e	The conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.
^a HealthyPeople.gov. Disparities. Available at: https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities . Published May 15, 2021.	
^b Centers for Disease Control and Prevention. Attaining Health Equity - Healthy Communities Program. Available at: https://www.cdc.gov/nccdphp/dch/programs/healthycommunitiesprogram/overview/healthequity.htm . Published May 29, 2019. Accessed June 1, 2021.	
^c FitzGerald C, Hurst S. Implicit bias in healthcare professionals: a systematic review. <i>BMC Med Ethics</i> . 2017;18:19. https://doi.org/10.1186/s12910-017-0179-8	
^d Bailey ZD, Krieger N, Agénor M, Graves J, Linos N, Bassett MT. Structural racism and health inequities in the USA: evidence and interventions. <i>Lancet</i> . 2017;389:1453-1463.	
^e Health.gov. Social Determinants of Health - Healthy People 2030. Available at: https://health.gov/healthypeople/objectives-and-data/social-determinants-health . Accessed June 1, 2021.	

trust within the therapeutic relationship, leading to low engagement with treatment, unwarranted care escalation, and poor health outcomes.^{2,19} Patient perceptions of discrimination and health care inequity reduce quality of care (an important component of value) even after accounting for potential confounders such as education level, English language proficiency, insurance coverage, and other indicators of access and satisfaction.²²

Two other key features of the physical therapy value proposition are (1) restoring function and participation and (2) cost savings from successful episodes of care.¹³ Both are negatively impacted by SDOH, which disproportionately affect different racial and ethnic groups.¹² For instance, lack of transportation, work and childcare schedules that prohibit availability for treatment during standard business hours, financial constraints, history of trauma, lack of Internet or technology resources (for telehealth), and

mental health needs can limit access to care, engagement with treatment, and potential benefits from physical therapists' services. While not all SDOH are modifiable within the health care system, if physical therapists do not overcome or address these constraints, it is to the detriment of potential gains in function and participation. Factors that are modifiable, such as implicit provider biases and judgments based on those bias, can be addressed. Doing so could improve care, reduce costs, and protect against unwarranted or avoidable escalation of care. The degree of cost savings is difficult to project as reductions in downstream costs would be at least partially offset by any upfront spending to effectively deliver equitable care (eg, addressing SDOH).

System and Environmental Factors Drive Inequitable LBP Care

Policies that influence health care payment and access also drive inequitable

care for LBP. Volume-based payment models (eg, fee-for-service) lack incentives for care coordination and service integration to address SDOH and behavioral and psychological needs.⁵ These needs have a higher prevalence and differential impact across various racial and ethnic groups, exacerbating potentially avoidable disparities in treatment outcomes. While most physical therapists are not in a position to directly influence payment, it is important they understand that key aspects of the delivery structure, such as how health care is funded, can independently facilitate inequities.

Structural racism (TABLE) is another system-level factor that can affect health care. One frequently cited example in the United States is unequal access to care in states that have not yet expanded Medicaid, a government-sponsored plan covering medical services for people with limited income and resources.²⁰ In states that have yet to expand Medicaid, African Americans and other people of color are disproportionately represented and particularly overrepresented among those living in poverty.^{8,20} The implications of this policy are especially relevant for LBP management, as populations commonly covered by Medicaid have high age-adjusted rates of chronic pain and high-impact chronic pain.⁶

Other structural contributors include lack of availability of evidence-based providers and services, or so-called "medical deserts," which have links to higher risk of opioid use and untreated or undertreated pain.¹⁴ Medical services tend to be concentrated in populated areas, creating few nonpharmacological, guideline-supported treatment options for LBP like physical and cognitive behavioral therapies in rural or other historically underserved and underresourced communities.

How the Physical Therapy Profession Can Promote and Support Equitable LBP Care

Like all health care providers, physical therapists have a moral and ethical responsibility to ensure equitable LBP care.

The Institute for Healthcare Improvement stated, “healthcare professionals can—and should—play a major role in seeking to improve health outcomes for disadvantaged populations.”¹⁷ We highlight 5 practical steps to assist physical therapists in promoting and delivering equitable care for LBP, with additional recommendations and resources provided in the **FIGURE** and a supplemental online table.

Get Informed Physical therapists must acknowledge that inequities are prevalent and damaging. They must also recognize factors that negatively affect care delivery and learn how these factors lead to disparate treatment. The onus for enhancing education on health equity falls on physical therapists themselves as well as academic programs that have an ethical responsibility to train graduates on how SDOH—including injustice, discrimination, and bias in health care access and delivery—affect patient health and treat-

ment outcomes and what can be done to address them. Stigma often results from systemic biases and discrimination and is perpetuated by the language providers use with their patients.²³

Recognize and Address Implicit Biases

Physical therapists must recognize that implicit biases are common yet modifiable and take steps to evaluate how these biases influence their clinical decision making. Implicit biases can create inaccurate perceptions of a patient’s prognosis, goals, treatment needs, or progress. Devine et al⁷ outline 5 strategies for reducing bias in health care: (1) recognize stereotypic responses and replace them with non-stereotypic responses, (2) imagine or think about a person who counters a popular stereotype, (3) view a person based on their personal characteristics rather than group-based attributes, (4) take the perspective of a person within the stigmatized group, and (5) seek opportunities to encounter or engage in

positive interactions with members of a stigmatized group. Many populations at risk for discrimination, or perceived discrimination, are disproportionately impacted by pain.¹⁰ Physical therapists have an opportunity to optimize their value as pain care providers by identifying and addressing implicit biases that compromise patient trust and confidence.

Assess Social Needs Identifying social needs, discussing their potential impact on outcomes with patients, and linking patients to resources when available are critical responsibilities of any direct access health care provider, especially those treating patients with LBP. The first step is identifying what resources are available and then building referral networks to match resources to patient needs. One innovative model being used by some pain management programs in underserved communities is a medical-legal partnership. This model connects medical and legal services to address needs like secure



Domain	Challenge	Strategies to address factors related to health inequity
Physical Therapist	Need for education on health disparities	Become informed on the impact and prevalence of inequities in LBP care Recognize and address implicit biases
	Unaddressed SDOH impacting treatment outcomes	Routinely assess social needs and social determinants of health Promote patient-centered shared decision making Practice guideline-supported care
	Structural characteristics that influence the patient experience and restrict equitable care	Promote diversity among health care providers Partner with payers to develop value-based payment programs
Health Care System	Medical deserts	Expand access to evidence-based pain care options in underserved communities
	Structural characteristics that restrict access to equitable care	Establish payment policies that facilitate the development and implementation of value-based, comprehensive LBP care programs Lobby for policies that address and overcome systemic racism
Environment & Policy	Limited knowledge on the prevalence and impact of disparate LBP care in physical therapy	Expand and prioritize health disparities research in physical therapy Determine risk factors for disparate care specific to LBP and across different settings where physical therapists provide care Identify treatments that impart value equally across populations Ensure appropriate representation of racial and ethnic groups in research
Research		

FIGURE. Strategies physical therapists can use to reduce inequitable care for LBP. Abbreviations: LBP, low back pain; SDOH, social determinants of health.

housing and disability benefits. Building partnerships with local and online resources provides opportunities to address modifiable social needs and would be especially critical as physical therapists take on direct access responsibilities.

The next step is to develop a systematic screening approach for social needs. The *Health Leads Social Needs Screening Toolkit*¹ is a comprehensive “how-to” guide for social needs screening that includes assessment of needs related to food insecurity, housing instability, financial strain, exposure to violence, transportation challenges, and others. Likewise, the CLEAR toolkit from McGill University is easily adapted to local contexts to help frontline health workers evaluate and address SDOH, particularly in low- and middle-income countries.⁴ Providers need training on how to have sensitive conversations about social needs with patients and the implications those needs have for treatment tailoring. Resources such as *Screening for Social Needs: Guiding Care Teams to Engage Patients* from the American Hospital Association¹ provide guidance for clinicians on how to develop and implement a social needs screening program.

Expand and Prioritize Health Disparities Research in Physical Therapy Much of what is known about disparate care for LBP comes from population-based surveys and research in primary care and emergency department settings. Health disparities research is not common in physical therapy, leaving questions regarding the exact prevalence and impact of disparate care by physical therapists. Absence of evidence is not proof that inequitable care does not exist in physical therapy. Important areas of future research in physical therapy include (1) better quantifying the prevalence and impact of disparate care by physical therapists, (2) determining risk factors for disparate care specific to LBP and across different settings where physical therapists provide care, (3) ensuring appropriate representation of different racial and ethnic groups in clinical research, and (4) iden-

tifying which treatments impart unequal value across populations. To address the latter, physical therapists should identify how to adapt existing interventions to account for non-modifiable SDOH and/or determine the applicability of existing interventions across different SDOH.

Promote and Support New Health Care Delivery and Payment Models for LBP Value-based payment models provide flexibility to coordinate care and address psychological and social needs through services not commonly reimbursed (or poorly reimbursed) through fee-for-service models (eg, nutritional counseling and mental and behavioral health care). While health care administrators and payers are largely responsible for the development and execution of these models, physical therapists can help drive a payment “revolution” by supporting lobbying efforts and professional organizations that advocate for payment and delivery reform.

A Renewed Call to Action

Ethical, equitable, and just care *is* high-value physical therapy; the physical therapy value proposition cannot be fully realized in the absence of this care. We endorse and build on Jewell et al’s¹³ call to action: underscoring the need to study, demonstrate, and advance equitable care for LBP by physical therapists. The most important result of these efforts will be improved outcomes for patients, but these efforts are also critical to ensuring the growth and sustainability of the physical therapy profession.

Key Points

- The growth and sustainability of physical therapy strongly depends on the ability to consistently demonstrate the value of services delivered by physical therapists for low back pain (LBP) across populations.
- Implicit provider biases, social determinants of health (SDOH), structural characteristics of the health care system, and inequitable health care policies hinder appropriate care and,

therefore, threaten the value of physical therapy.

- Physical therapists can take important steps to improve equity of care for LBP by recognizing and addressing implicit biases (individual, systemic, and structural), assessing social needs, expanding and prioritizing disparities research in physical therapy, and advocating for new payment models that incentivize providers to better address SDOH. ●

STUDY DETAILS

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Recurrence of an Episode of Low Back Pain: An Inception Cohort Study in Emergency Departments

The prognosis of acute low back pain (LBP) is widely described as favorable.⁵ Recurrences of LBP are common.^{20,33} There are few inception cohort studies (ie, participants admitted at an early and uniform point in the disease course) investigating LBP recurrences.^{9,22,36} Recurrence estimates ranged from 24%³⁶ to 69%⁹ in patients from primary care practices in high-income countries, and few studies have investigated predictors of recurrence.^{9,22,36} Previous LBP was the only consistent prognostic factor associated with recurrence.^{9,22,36}

Patients with LBP frequently present to emergency departments (EDs),¹⁴ despite practice guidelines advocating for first-line treatment in primary care

settings. LBP was 1 of the top 5 reasons for seeking care at EDs in middle- and high-income countries.¹¹ When stratified by the health system, the prevalence of LBP was similar in private and public systems.¹¹

According to the Brazilian National Health Survey, 1 in every 3 patients had visited an ED in the last 6 months. Musculoskeletal conditions were the most common reason for presenting.¹⁵ Brazil is a middle-income country where the public health system guarantees free primary, secondary, and tertiary health care.³⁹ However, Brazilians can also pay for health care providers at the time of service or join a health insurance plan.¹³ According to recent estimates, 28% of the Brazilian population has private health insurance.^{24,29}

Recent guidelines for LBP recommended the use of risk stratification tools, such as the STarT Back Screening Tool (SBST).^{23,27} The SBST was developed to stratify patients and to recommend treatment.¹⁹ People in different SBST risk strata may present different risks for the recurrence of an LBP episode and have different prognoses.

We aimed to (1) determine the 1-year estimate of recurrence of LBP in a cohort

● **OBJECTIVES:** To (1) determine the 1-year estimate of recurrence of low back pain (LBP) in a cohort of people presenting to emergency departments who have recently recovered from an episode of acute LBP in a middle-income country, (2) estimate a recurrence of LBP stratified by the STarT Back Screening Tool (SBST), and (3) determine prognostic factors for the recurrence of LBP.

● **DESIGN:** Prospective inception cohort study.

● **METHODS:** We included 238 patients who presented to emergency departments with recent-onset nonspecific LBP in São Paulo, Brazil. The outcome was the recurrence of an episode of LBP, assessed using 2 definitions: (1) 12-month recall alone and (2) pain measurements at follow-up. Prognostic factors were determined by logistic regression.

● **RESULTS:** Within 1 year, the estimated recurrence of an episode of LBP ranged from 35% (79/225 events) (first definition) to 44% (100/226

events) (second definition). When patients were stratified by the SBST, the estimate of recurrence ranged from 29% to 37% (21-27/73 events) for low-risk patients, from 33% to 39% (24-28/72 events) for medium-risk patients, and from 43% to 56% (34-45/80 events) for high-risk patients. Age, perceived risk of persistent LBP, and disability were independent prognostic factors associated with LBP recurrence within 1 year.

● **CONCLUSION:** After recovering from a previous episode of acute LBP, 4 in every 10 patients experienced a recurrence within 1 year. This estimate varied depending on the classification used in the SBST. Within 1 year, age, perceived risk of persistent LBP, and baseline disability were predictors of recurrence. *J Orthop Sports Phys Ther* 2022;52(7):484-492. Epub: 18 May 2022. doi:10.2519/jospt.2022.10775

● **KEY WORDS:** cohort studies, incidence, low back pain, prognosis, recurrence, risk

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of people presenting to EDs who had recently recovered from an episode of acute LBP in a middle-income country, (2) estimate a recurrence of LBP stratified by the SBST, and (3) identify the prognostic factors associated with the recurrence of LBP.

METHODS

THIS IS A SECONDARY ANALYSIS OF A prospective inception cohort study that investigated the long-term prognosis of recent-onset LBP in people from EDs.²⁸ This study recruited consecutive patients with recent-onset nonspecific LBP in EDs at 4 public hospitals in São Paulo, Brazil, from August 2015 to August 2017. The selected hospitals are located in 4 (west, east, south, and southwestern) of the 9 zones of the city of São Paulo. Ethics approval for the original study was granted by the Universidade Cidade de São Paulo (25315713.7.0000.0064). Informed consent was obtained from all participants.

Participants

The sample of the original study comprised 600 patients aged 18 to 80 years with acute nonspecific LBP with or without leg pain who sought care in EDs. Nonspecific LBP was defined as pain between the 12th rib and the buttock crease not attributed to a specific diagnosis lasting more than 24 hours, preceded by a period of at least 1 month without pain.^{17,38} Acute LBP was defined as pain lasting for less than 6 weeks.^{21,38}

Patients with serious spinal pathologies, patients with nerve root compromise, patients who were pregnant, non-Portuguese speakers, patients with chronic LBP, and patients with renal dysfunction were excluded.

For this analysis, we included only participants who had recovered by the 6-week follow-up: only patients in whom recurrence was possible were included. Recovery from pain was defined as having no pain for 30 consecutive days,^{6,18} assessed by asking 2 questions: (1) Have you been completely pain-free in the last 6 weeks? (2) Have you been pain-free for

at least 30 consecutive days? Patients who answered “yes” to both questions were classified as recovered and included in this study.

Study Procedures

Following usual hospital care, patients were seen by a clinician who provided medical consultation. Patients were then referred to 1 member of our research team for data collection. The researcher screened for eligibility; obtained consent; and collected baseline data using a paper booklet, reading all questions to the study participants. After baseline assessment, the same researcher contacted participants via e-mail, text message, WhatsApp, or phone (based on patient preference) to collect information on pain intensity at 6 weeks, 3, 6, and 12 months, as well as recurrence at 12 months.

Outcome

The primary outcome was the recurrence of an episode of LBP defined as a return of LBP lasting at least 24 hours, with a pain intensity greater than 2 on an 11-point

numeric rating scale (NRS) preceded by a pain-free period of at least 1 month.³⁷ This definition was obtained from a Delphi study³⁷ and has been widely used.^{9,16,22}

Recurrence was assessed using 2 definitions: (1) using 12-month recall alone, by asking, “Since the date of your recovery, have you had an episode of LBP lasting longer than 24 hours?” Patients who answered “yes” to this question were classified as having a recurrence; and (2) assessing the average pain intensity of LBP during the past week on an 11-point NRS.^{2,3,34} Information was collected at 3-, 6-, and 12-month follow-up. This was done to avoid recall bias. Participants who reported a pain intensity greater than 2 at any of the follow-ups were considered to have a recurrence.^{22,37}

The 1-year estimate of recurrence was described considering all participants and by stratifying participants according to the SBST at baseline. The SBST includes 9 items on modifiable physical and psychosocial factors, and the total score ranges from 0 to 9 points. If the total score is between 0 and 3 points,

TABLE 1

**CANDIDATE PROGNOSTIC FACTORS
FOR A RECURRENCE OF LOW BACK PAIN**

Candidate Prognostic Factor	Data Format at Collection	Coding of Data in the Model
Age	Age in years (continuous)	Continuous
Duration of previous episode	How long did your most recent episode of low back pain last (days)? (continuous)	Continuous
History of previous LBP episodes	Did you have previous episodes of low back pain? (yes, no)	Dichotomous: yes, no
Risk of persistent LBP	In your view, how large is the risk that your current pain may become persistent? Measured on a 0-10 scale, where 0 = no risk and 10 = very large risk (continuous)	Continuous
Feelings of depression	How much have you been bothered by feeling depressed in the past week? Measured on a 0-10 scale, where 0 = not at all and 10 = extremely (continuous)	Continuous
Pain intensity	Numeric pain rating scale: I would like you to rate your pain on a scale from 0 to 10, where 0 is no pain and 10 is the worst possible pain. Please give a number to describe your average pain over the last 7 days (continuous)	Continuous
Disability	Roland-Morris Disability Questionnaire	Continuous

Abbreviation: LBP, low back pain.

the patient is classified as “low risk” for unfavorable prognosis. If the total score is above 3 points, only the psychosocial subscale (corresponding to items 5 through 9 on the instrument) is calculated. Scores between 0 and 3 on the subscale are classified as “medium risk” for unfavorable prognosis. Scores above 3 on the subscale are classified as “high risk” for unfavorable prognosis.^{19,35} The Brazilian-Portuguese version of the SBST has excellent reliability ($ICC_{2,1} = 0.79$), internal consistency (Cronbach α ranging from 0.72 to 0.74), and standard error of measurement of 1.9%.³²

Predictors

At baseline, demographic data and potential prognostic factors for the recurrence of LBP were collected. Seven a priori prognostic factors were selected as predictive of LBP recurrence based on the existing literature or biological plausibility: age, duration of previous LBP episode,^{9,16,22} history of previous LBP episodes,³⁶ perceived risk of persistent LBP,¹² feelings of depression,¹² pain intensity, and disability at baseline.⁷ **TABLE 1** describes factors and how they were measured and coded.

Sample Size

A formal power calculation was not performed for the questions about recurrence, as it was not the primary aim of the data collection. However, it is important to understand how many possible prognostic factors may be investigated in the secondary analysis based on sample size. The sample size of 225 participants should provide a relatively accurate estimate of recurrence, considering that the estimate of recurrence of previous studies^{22,36} was 33% and the precision of the estimate was 6 percentage points, ie, a 95% confidence interval (CI) of 27% to 39%. Regarding the aim of prognostic factors, previous studies recommend at least 10 events per candidate variable in the multivariable model.^{30,31} Based on the 33% recurrence estimate, a sample of 225 participants would yield 74 events, allow-

ing for the investigation of a maximum of 7 candidate predictor variables in the model.

Missing Data

We used a complete-case analysis by excluding participants with missing data at any follow-up for the analyses about recurrence proportions and prognostic factors

for a recurrence. The **APPENDIX** provides information comparing distributions of key exposure variables for patients with missing and non-missing information.

Statistical Analysis Methods

The estimate of recurrence of an episode of LBP and the estimate of recurrence stratified by the SBST were assessed by

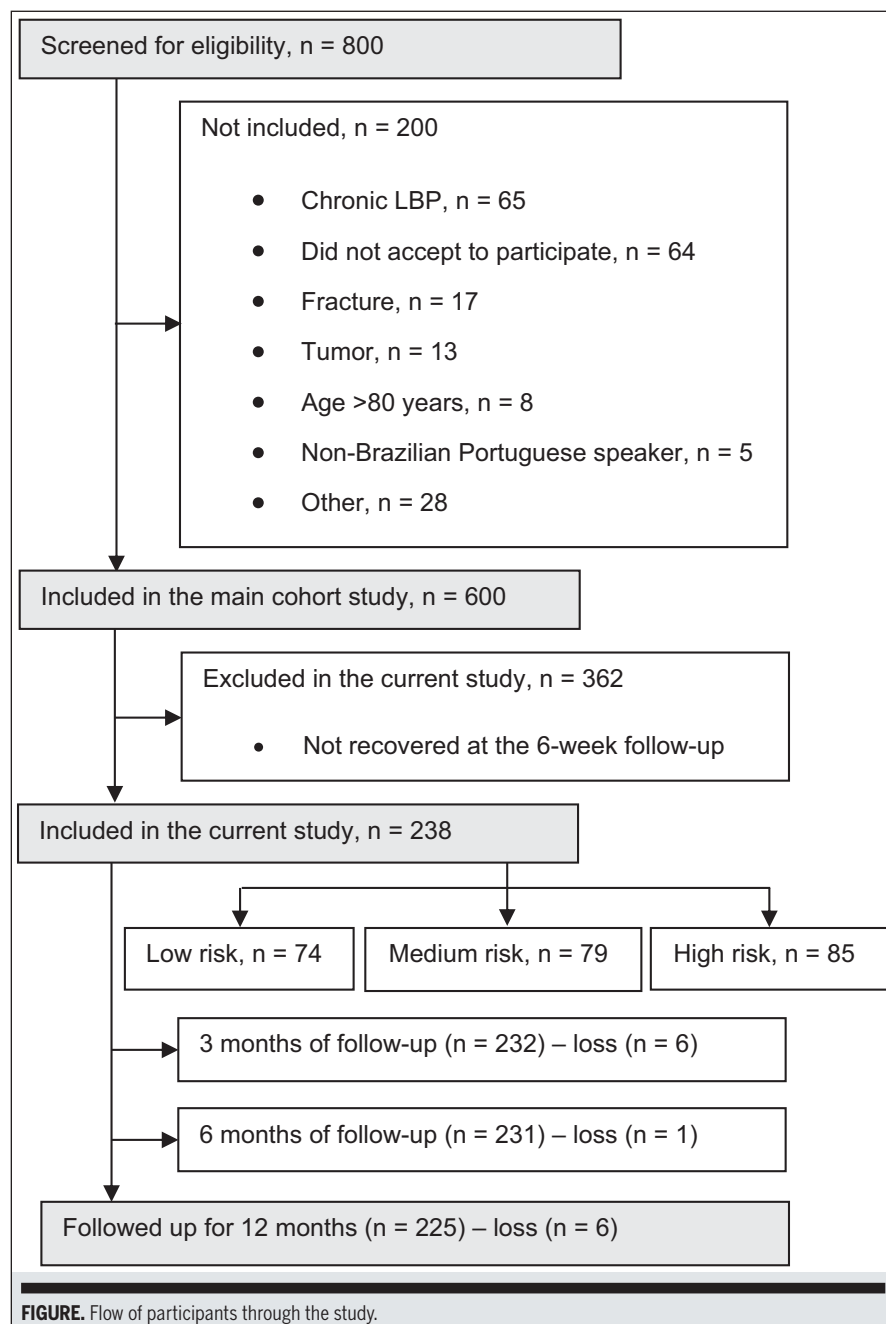


FIGURE. Flow of participants through the study.

TABLE 2

BASELINE DEMOGRAPHIC CHARACTERISTICS OF ALL THE STUDY PARTICIPANTS
AND ACCORDING CLASSIFICATION FROM THE STarT BACK SCREENING TOOL

Variables	All (n = 238)	95% CI	Low Risk (n = 74)	95% CI	Medium Risk (n = 79)	95% CI	High Risk (n = 85)	95% CI
Sex, n (%)								
Female	131 (55.0)	48.7, 61.2	36 (48.7)	37.6, 59.8	47 (59.5)	48.5, 69.6	48 (56.5)	45.9, 66.5
Male	107 (45.0)	38.8, 51.3	38 (51.3)	40.2, 62.4	32 (40.5)	30.4, 51.5	37 (43.5)	33.5, 54.1
Age (y), mean (SD)	41.3 (14.2)	—	38.7 (13.8)	—	40.4 (13.0)	—	44.5 (15.6)	—
Body mass index (kg/m^2), mean (SD)	26.6 (5.0)	—	26.2 (4.0)	—	27.0 (5.7)	—	26.4 (5.1)	—
Education level, n (%)								
Illiterate	1 (0.4)	0.07, 0.2	1 (1.4)	0.02, 0.7	2 (2.5)	0.7, 8.7	4 (4.7)	1.9, 11.5
Primary school	62 (26.1)	20.9, 40.0	14 (18.9)	11.6, 29.3	16 (20.3)	12.9, 30.4	30 (35.3)	26.0, 45.9
Secondary school	109 (45.8)	39.6, 52.1	35 (47.3)	36.3, 58.5	36 (45.6)	35.1, 56.5	38 (44.7)	34.6, 55.3
Undergraduate university	49 (20.6)	15.9, 26.2	19 (25.7)	17.1, 36.7	20 (25.3)	17.0, 35.9	10 (11.8)	6.5, 20.3
Postgraduate university	13 (5.4)	3.2, 9.1	5 (6.8)	2.9, 14.7	5 (6.3)	2.7, 14.0	3 (3.5)	1.2, 9.9
Worker's compensation, n (%)								
Yes	13 (5.5)	3.2, 9.1	2 (2.7)	0.7, 9.3	5 (6.3)	2.7, 14.0	6 (7.1)	3.3, 14.6
No	225 (94.5)	90.9, 96.8	72 (97.3)	90.7, 99.3	74 (93.7)	86.0, 97.3	79 (92.9)	85.4, 96.7
General health, n (%)								
Excellent	38 (16.0)	11.9, 21.2	19 (25.7)	17.1, 36.7	11 (13.9)	8.0, 23.2	8 (9.4)	4.9, 17.5
Very good	55 (23.1)	18.2, 28.9	20 (27.0)	18.2, 38.0	26 (32.9)	23.6, 43.9	9 (10.6)	5.7, 18.9 ^a
Good	114 (47.9)	41.6, 54.2	33 (44.6)	33.8, 55.9	35 (44.3)	33.9, 55.3	46 (54.1)	43.6, 64.3
Fair	25 (10.5)	7.2, 15.1	2 (2.7)	0.7, 9.3	4 (5.1)	2.0, 12.3	19 (22.4)	14.8, 32.3 ^a
Poor	6 (2.5)	1.2, 5.4	0 (0)	0.0, 0.0	3 (3.8)	1.3, 10.6	3 (3.5)	1.2, 9.9
Smoking, n (%)								
Yes	56 (23.5)	18.6, 29.3	15 (20.3)	12.7, 30.8	18 (22.8)	14.9, 33.2	23 (27.1)	18.8, 37.3
No	182 (76.5)	70.7, 81.4	59 (79.7)	69.2, 87.3	61 (77.2)	66.8, 85.1	62 (72.9)	62.7, 81.2
Duration of previous episode, mean (SD)	71 (7.6)	—	71 (8.5)	—	6.2 (6.2)	—	79 (8.0)	—
History of previous episode of LBP, n (%)								
Yes	156 (65.5)	59.3, 71.3	44 (59.5)	48.1, 69.9	53 (67.1)	56.2, 76.5	59 (69.4)	59.0, 78.2
No	82 (34.5)	28.7, 40.7	30 (40.5)	30.1, 51.9	26 (32.9)	23.6, 43.9	26 (30.6)	21.8, 41.1
Pain that extends to the leg, n (%)								
Yes	107 (45.0)	38.8, 51.3	20 (27.0)	18.2, 38.0	44 (54.6)	44.7, 66.1 ^a	43 (50.6)	40.2, 61.0
No	131 (55.0)	48.7, 61.2	54 (73.0)	61.9, 81.8	35 (45.4)	33.9, 55.3 ^a	42 (49.4)	39.0, 59.8
Perceived risk of persistent LBP (0-10), mean (SD)	5.3 (3.5)	—	4.0 (3.1)	—	5.0 (3.1)	—	6.6 (3.5)	—
Stress and anxiety (0-10), median (IQR)	8.0 (4-10)	—	5.0 (2-8)	—	8.0 (3-9)	—	9.0 (7-10)	—
Feelings of depression (0-10), median (IQR)	4.0 (0-8)	—	0.5 (0-5)	—	4.0 (0-8)	—	6.0 (2.5-9)	—
Pain intensity (0-10), mean (SD)	7.5 (2.1)	—	6.4 (2.3)	—	7.7 (1.8)	—	8.1 (1.9)	—
Disability (Roland-Morris), median (IQR)	16 (10-20)	—	9 (4-13)	—	17 (13-19)	—	20 (14-22)	—
Interference with function, n (%)								
Not at all or a little bit	145 (60.9)	54.6, 66.9	56 (75.7)	64.8, 84.0	51 (64.6)	53.6, 74.2	38 (44.7)	34.6, 55.3
Moderate	48 (20.2)	15.6, 25.7	15 (20.3)	12.7, 30.8	11 (13.9)	8.0, 23.2	22 (25.9)	17.8, 36.1
Quite a bit or extreme	45 (18.9)	14.4, 24.4	3 (4.1)	1.4, 11.3	17 (21.5)	13.9, 31.8 ^a	25 (29.4)	20.1, 39.8
Recovery from pain (days), mean (SD)	18.1 (11.2)	—	12.5 (10.6)	—	19.4 (11.2)	—	19.2 (11.3)	—

Abbreviations: CI, confidence interval; IQR, interquartile range; LBP, low back pain; SD, standard deviation.

^aStatistically significant difference STarT Back Screening Tool classification when comparing participants' characteristics (no overlap of the 95% CIs).

— Information about CIs was not provided for continuous variables, as it was presented as mean (SD) or median (IQR).

the proportion of patients who had a recurrence divided by the total number of patients with potential for a recurrence.

CI's were calculated using an online calculator.⁴ The estimate was presented according to the 2 definitions.

The analysis by which significant prognostic factors were identified is exploratory, as this is the first study investigating

recurrences of LBP in patients from EDs. Multicollinearity of predictor variables was assessed by regression analysis using correlation coefficients and a variance inflation factor. First, we ran univariable logistic regression models to test whether there was a relationship between each variable and time to recurrence. These were used to understand the univariable associations and help interpret the multivariable model eligibility for the multivariable model. Multivariable logistic regression analysis was then performed, using the enter method. The recurrence outcome was analyzed using the 2 definitions. All analyses were performed using SPSS Statistics (Version 22.0; IBM Corporation, Armonk, NY).

RESULTS

Of the 600 participants of the original cohort study, 362 were excluded as they had not recovered at 6 weeks. Of the 238 included participants, 74 were classified as “low risk” for unfavorable prognosis, 79 were classified as “medium risk” for unfavorable prognosis, and 85 were classified as “high risk” for unfavorable prognosis. Thirteen patients were lost to follow-up; 225 participants (94.5%) were followed up during the 12 months (FIGURE).

The mean age of participants was 41 years; 55% were female, and 48% described their general health as good (TABLE 2). The mean duration of symptoms was 7 days, and the mean duration of recovery from pain was 11 days. Patients reported high levels of pain intensity and disability. The mean pain intensity score was 7.5 according to the 0- to 10-point NRS, and the median disability score was 16 according to the 24-item Roland-Morris Disability Questionnaire.

In general, there was no statistically significant difference between demographic and pain characteristics when comparing risk groups according to the SBST (by analyzing 95% CI overlap). Participants in the high-risk group reported

having fair general health more frequently when compared to participants in low- and medium-risk groups. Participants in the medium-risk group reported having pain that extends to the leg more frequently when compared to participants in the low-risk group. Participants in the medium-risk group reported having quite a bit or extreme interference with function more frequently when compared to participants in the low-risk group.

Recurrence of an Episode of LBP/ Recurrence of an Episode of LBP Stratified by the SBST

Using the definition *recurrence based on 12-month recall alone*, the probability of recurrence of an episode of LBP at 12 months was 35% (95% CI: 29%, 41%; 79/225 events). Stratifying participants by the SBST, the probability of a recurrence of an episode of LBP at 12 months

for participants classified as “low risk” was 29% (95% CI: 20%, 40%; 21/73 events), that for participants classified as “medium risk” was 33% (95% CI: 24%, 45%; 24/72 events), and that for participants classified as “high risk” was 43% (95% CI: 32%, 53%; 34/80 events).

Using the definition *recurrence based on pain measures taken at 3-, 6-, and 12-month follow-ups*, the probability of recurrence of an episode of LBP at 12 months was 44% (95% CI: 38%, 51%; 100/226 events). Stratifying participants by the SBST, the probability of a recurrence of an episode of LBP at 12 months for participants classified as “low risk” was 37% (95% CI: 27%, 49%; 27/73 events), that for participants classified as “medium risk” was 39% (95% CI: 29%, 50%; 28/72 events), and that for participants classified as “high risk” was 56% (95% CI: 45%, 67%; 45/80 events).

TABLE 3

UNIVARIABLE ANALYSIS FOR A RECURRENCE
OF AN EPISODE OF LBP

Prognostic Factor	Recurrence (n/total n) ^a	Odds Ratio	95% CI	P Value
<i>Recurrence measured via 12-month recall alone</i>				
Age	N/A	1.03	1.01, 1.05	.003
Duration of previous episode	N/A	1.01	0.98, 1.05	.427
History of previous episode of LBP				
No	90/146	Reference	—	—
Yes	59/79	1.84	1.00, 3.37	.050
Perceived risk of persistent LBP	N/A	1.16	1.06, 1.26	.001
Feelings of depression	N/A	1.05	0.98, 1.13	.200
Pain intensity	N/A	1.02	0.90, 1.16	.728
Disability	N/A	1.07	1.02, 1.12	.006
<i>Recurrence measured using pain measures taken at follow-ups</i>				
Age	N/A	1.01	0.99, 1.03	.298
Duration of previous episode	N/A	1.01	0.98, 1.05	.462
History of previous episode of LBP				
No	102/163	Reference	—	—
Yes	47/62	1.58	0.90, 2.79	.112
Perceived risk of persistent LBP	N/A	1.17	1.08, 1.27	>.001
Feelings of depression	N/A	1.12	1.04, 1.21	.002
Pain intensity	N/A	1.11	0.97, 1.25	.121
Disability	N/A	1.09	1.04, 1.15	.001

Abbreviations: CI, confidence interval; LBP, low back pain; N/A, not applicable.

^aNumber of participants who had the event in each category/total number of participants in each category.
— Information about odds ratio, CIs and P value was not provided for the reference category in cases of categorical variables.

Prognostic Factors for a Recurrence of an Episode of LBP

The results of the univariable analyses are shown in **TABLE 3**. There was no evidence that any of the predictor variables violated the linearity assumption for both outcomes. Of the 8 variables included in the multivariable model, age (odds ratio [OR] = 1.03; 95% CI: 1.01, 1.05), perceived risk of persistent LBP (OR = 1.14; 95% CI: 1.04, 1.26), and disability (OR = 1.06; 95% CI: 1.00, 1.12) were associated with *recurrence based on 12-month recall alone*. Age (OR = 1.03; 95% CI: 1.01, 1.05), perceived risk of persistent LBP (OR = 1.16; 95% CI: 1.06, 1.29), and disability (OR = 1.07; 95% CI: 1.00, 1.13) were associated with *recurrence based on pain measures taken at 3-, 6-, and 12-month follow-ups* (**TABLE 4**).

DISCUSSION

FOUR IN EVERY 10 PATIENTS WITH LBP who visited an ED had a recurrence of their LBP in 12 months. When patients were stratified by the SBST, there was no important between-group difference considering both definitions for most of the variables. Age, perceived risk of persistent LBP, and disability were independent prognostic factors associated with recurrence of LBP within 1 year.

Strengths and Limitations

This is the first study investigating estimates of recurrence of LBP in patients who visited EDs, and to describe estimates of recurrence based on the SBST classification. We used data from a large inception cohort of ED patients seeking care for their LBP, with minimal loss to

follow-up.²⁸ An acceptable definition of pain recovery was used to include patients in the study.^{6,18} Only patients who had fully recovered after their index episode of LBP were included. Finally, recurrence was measured using standardized definitions of an episode of LBP,³⁸ resulting in a comprehensive, accurate estimate of recurrence at 1 year.

This study also had some limitations. First, although we enrolled consecutive participants, some potentially eligible participants may not have been informed of the study by their clinicians and were not included. Also, although we included patients from hospitals located in 4 of the 9 zones of the city of São Paulo, the sample may not be fully representative of all persons seeking care in EDs for LBP. Second, information on all prognostic factors was collected using self-report, and we recognize that some objective measures (eg, strength) may have predicted recurrence. In addition, some of the measures have not been validated. Third, in our study, recurrence was determined by a question asked only after 1 year of follow-up. This factor can be considered an important limitation due to recall bias.⁸ To minimize this limitation, we used a second definition for estimating recurrence by considering patients who had 2 or more pain intensity scores at different time points. Finally, we did not collect details about socioeconomic factors that may influence recurrences. We also did not collect information on the interventions that participants received during the previous LBP episode, which may have influenced the percentage of people with recurrence.

Interpretation

Our estimates were higher than estimates reported in 2 previous studies conducted with patients from primary care using the same recurrence definition.^{22,36} Stanton et al³⁶ reported a 1-year estimate of recurrence ranging from 24% (95% CI: 20%, 28%) using the “12-month recall” definition to 33% (95% CI: 28%, 38%) using the “pain at follow-up” definition. Machado et al²² used the same definitions and found a 1-year estimate

TABLE 4

MULTIVARIABLE ANALYSIS FOR A RECURRENCE OF AN EPISODE OF LBP

Prognostic Factor	Recurrence (n/total n) ^a	Odds Ratio	95% CI	P Value
<i>Recurrence measured via 12-month recall alone</i>				
Age	N/A	1.03	1.01, 1.05	.008
Duration of previous episode	N/A	1.01	0.97, 1.05	.604
History of previous episode of LBP				
No	90/146	Reference	—	—
Yes	59/79	1.40	0.72, 2.69	.319
Perceived risk of persistent LBP	N/A	1.14	1.04, 1.26	.005
Feelings of depression	N/A	1.00	0.92, 1.09	.968
Pain intensity	N/A	0.93	0.80, 1.09	.365
Disability	N/A	1.06	1.00, 1.12	.043
<i>Recurrence measured using pain measures taken at follow-ups</i>				
Age	N/A	1.03	1.01, 1.05	.008
Duration of previous episode	N/A	1.00	0.96, 1.04	.931
History of previous episode of LBP				
No	102/163	Reference	—	—
Yes	47/62	1.32	0.64, 2.73	.454
Perceived risk of persistent LBP	N/A	1.17	1.06, 1.29	.003
Feelings of depression	N/A	1.04	0.95, 1.14	.394
Pain intensity	N/A	1.01	0.85, 1.20	.944
Disability	N/A	1.07	1.00, 1.13	.042

Abbreviations: CI, confidence interval; LBP, low back pain; N/A, not applicable.

^aNumber of participants who had the event in each category/total number of participants in each category.

— Information about odds ratio, CIs and P value was not provided for the reference category in cases of categorical variables.

of 33% based on 12-month recall. The differences between estimates could be due to differences in the severity of LBP in patients attending EDs compared to patients who were seeking care in a primary health care setting. da Silva et al⁹ found that within 1 year, 69% (95% CI: 62, 74) of participants had a recurrence of an episode of LBP and about 40% of participants reported moderate activity limitation or that health care was sought. The estimates of recurrence with activity limitation and for which health care was sought were similar to the estimate of the present study. Patients may remember substantial recurrences when asked after 12 months.

The factors associated with recurrence in the current study also differ from those in previous studies conducted in primary care.^{22,36} The estimate of recurrence did not differ between SBST risk groups. This indicates that the SBST may not inform clinicians about recurrences of LBP in people who seek care in EDs but can be useful to guide patient education about follow-up care after the ED interaction. However, this would need to be investigated.

Implications

Despite guidelines indicating that LBP should be managed in primary care, patients with LBP frequently present to EDs.¹⁴ ED providers must inform their patients that after recovering from an episode of LBP, recurrence may occur in approximately 4 in 10 patients within 1 year. Sharing this information can help ensure that patients have realistic expectations about their risk of recurrence after recovery from an episode of LBP. Another clinical implication is the potential use and importance of secondary prevention strategies for patients after they recover from an episode of LBP.

Recent guidelines also indicate that the existing evidence developed for high-income countries can be applied in low- and middle-income countries. However, it might need adaptations to assure feasibility and cultural appropriateness for

low-resource settings.¹⁴ Our results highlight the importance of investigation of differences related to health status and health care reported by patients with LBP in low-, middle-, and high-income countries and how health care systems in low-, medium-, and high-income countries may affect outcomes in patients with LBP and the choices of health care providers.

Future studies may investigate the best approach to quantifying recurrence and the best definition of a recurrence. Estimates based on the consensus definition of a recurrence³⁸ include recurrences that may have little impact.¹⁰ Future studies can also better investigate the utility of the SBST in EDs. Previous studies have identified changes in SBST categorization over time in LBP patients visiting primary care after 4 weeks¹ and 5 weeks²⁵ and in patients visiting EDs at 6 weeks,²⁶ showing that the discrimination of the tool is improved when collected a few weeks after the baseline.

CONCLUSION

AFTER RECOVERING FROM A PREVIOUS episode of acute LBP, 4 in every 10 individuals will have a recurrence in 1 year. There was no difference in estimates between risk groups when patients were stratified by the SBST. Within 1 year, age, perceived risk of persistent LBP, and baseline disability were predictors of recurrence. ●

KEY POINTS

FINDINGS: After recovering from a previous episode of acute low back pain (LBP), 4 in every 10 people will experience a recurrence within 1 year. When patients were stratified by the STarT Back Screening Tool (SBST), there was no difference between groups. Age, perceived risk of persistent LBP, and disability are predictors of recurrence within 1 year.

IMPLICATIONS: These findings are important for providers when informing patients about the likely risk of recurrences of LBP. Future studies can explore differences related to health status and health

care in low-, middle-, and high-income countries; the best approach of recurrence to use; and the utility of the SBST in emergency departments.

CAUTION: Recurrence of an episode of LBP was only asked after a follow-up period of 12 months. Information about interventions participants had received during the previous episode of LBP was not collected, which may have influenced the percentage of people with a recurrence.

STUDY DETAILS

AUTHOR CONTRIBUTIONS: All authors were involved in developing the design of the study. Drs Medeiros and Oliveira were involved in the recruitment of participants, data collection, and data entry. Dr da Silva did the statistical analysis and interpretation of data in consultation with Drs Medeiros, Menezes Costa, and Pena Costa. Drs da Silva and Medeiros wrote the first draft. All authors also contributed by reviewing previous versions of the manuscript and improving the final version. Drs da Silva, Medeiros, and Menezes Costa had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

DATA SHARING: Data are available on request.

PATIENT AND PUBLIC INVOLVEMENT: Patients were not involved in the design, conduct, interpretation, and/or translation of the study.

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APPENDIX

KEY BASELINE DEMOGRAPHIC CHARACTERISTICS OF ALL THE STUDY PARTICIPANTS, PARTICIPANTS WITHOUT MISSING DATA, AND PARTICIPANTS WITH MISSING DATA

Variables	All (n = 238)	Patients Without Missing Data (n = 225)	Patients With Missing Data (n = 13)
Sex, n (%; 95% CI)			
Female	131 (55.0; 48.7, 61.2)	126 (56.0; 49.5, 62.3)	5 (38.5; 17.7, 64.5)
Age (y), mean (SD)	41.3 (14.2)	41.3 (14.2)	40.2 (13.9)
Body mass index (kg/m^2), mean (SD)	26.6 (5.0)	26.7 (5.1)	24.4 (3.4)
Education level, n (%; 95% CI) ^a			
Illiterate	1 (0.4; 0.07, 2.3)	1 (0.4; 0.08, 2.5)	0 (0; 0, 0)
Primary school	62 (26.1; 20.9, 32.0)	58 (25.8; 20.5, 31.9)	4 (30.8; 12.7, 57.6)
Secondary school	109 (45.8; 40.0, 52.1)	103 (45.8; 39.4, 52.3)	6 (46.2; 23.2, 70.9)
Undergraduate university	49 (20.6; 15.9, 26.2)	46 (20.4; 15.7, 26.1)	3 (23.1; 8.2, 50.3)
Postgraduate university	13 (5.4; 3.2, 9.1)	13 (5.8; 3.4, 9.6)	0 (0; 0, 0)
General health, n (%; 95% CI)			
Excellent	38 (16.0; 11.9, 21.2)	34 (15.1; 11.0, 20.4)	4 (30.8; 12.7, 57.6)
Very good	55 (23.1; 18.2, 28.9)	52 (23.1; 18.1, 29.0)	3 (23.1; 8.2, 50.3)
Good	114 (47.9; 41.6, 54.2)	110 (48.9; 42.4, 55.4)	4 (30.8; 12.7, 57.6)
Fair	25 (10.5; 7.2, 15.1)	23 (10.2; 6.9, 14.9)	2 (15.4; 4.3, 42.2)
Poor	6 (2.5; 1.2, 5.4)	6 (2.7; 1.2, 5.7)	0 (0; 0, 0)
Smoking, n (%; 95% CI)	56 (23.5; 18.6, 29.3)	56 (23.5; 19.7, 30.9)	3 (23.1; 8.2, 50.3)
Duration of previous episode, mean (SD)	7.1 (7.6)	7.0 (7.6)	7.7 (7.9)
History of previous episode of LBP, n (%; 95% CI)	156 (65.5; 59.3, 71.3)	149 (66.2; 59.8, 72.1)	7 (53.8; 29.1, 76.8)
Pain that extends to the leg, n (%; 95% CI)	107 (45.0; 38.8, 51.3)	99 (44.0; 37.7, 50.5)	6 (46.2; 23.2, 70.9)
Perceived risk of persistent LBP (0-10), mean (SD)	5.3 (3.5)	5.1 (3.5)	6.2 (3.7)
Stress and anxiety (0-10), median (IQR)	8.0 (4-10)	8.0 (4-10)	10 (1-10)
Feelings of depression (0-10), median (IQR)	4.0 (0-8)	4.0 (0-7.5)	8 (0-10)
Pain intensity (0-10), mean (SD)	7.5 (2.1)	7.4 (2.1)	8.2 (1.8)
Disability (Roland-Morris), median (IQR)	16 (10-20)	15 (10-19)	18.2 (15-21.5)
Interference with function, n (%; 95% CI)			
Not at all or a little bit	145 (60.9; 54.6, 66.9)	136 (60.4; 53.9, 66.7)	9 (69.2; 42.4, 87.3)
Moderate	48 (20.2; 15.6, 25.7)	45 (20.0; 15.3, 25.7)	3 (23.1; 8.2, 50.3)
Quite a bit or extreme	45 (18.9; 14.4, 24.4)	44 (19.6; 14.9, 25.2)	1 (7.7; 1.4, 33.3)

Abbreviations: CI, confidence interval; IQR, interquartile range; LBP, low back pain; SD, standard deviation.

^aThere was less than 1% missing value for this variable.